

**IN THE COURT OF COMMON PLEAS  
FOR MONTGOMERY COUNTY, PENNSYLVANIA**

**INTERNATIONAL UNION OF OPERATING  
ENGINEERS LOCAL 542**

Plaintiff,

v.

Civil Action No. 2018-14059

**MALLINCKRODT ARD, INC., *et al.***

Defendants.

**ORDER**

AND, NOW, this \_\_\_\_\_ day of \_\_\_\_\_, 2019, upon consideration of Plaintiff International Union of Operating Engineers Local 542's Motion to Strike Defendants Mallinckrodt ARD, Inc.'s and Mallinckrodt plc's Objections to Subpoenas ("Motion"), it is hereby ORDERED and DECREED that the Motion is DENIED.

BY THE COURT

\_\_\_\_\_  
Steven C. Tolliver, Sr.

IN THE COURT OF COMMON PLEAS  
FOR MONTGOMERY COUNTY, PENNSYLVANIA

**INTERNATIONAL UNION OF OPERATING  
ENGINEERS LOCAL 542**

Plaintiff,

v.

Civil Action No. 2018-14059

**MALLINCKRODT ARD, INC., *et al.***

Defendants.

**DEFENDANTS MALLINCKRODT ARD, INC.'S AND MALLINCKRODT PLC'S  
OPPOSITION TO PLAINTIFF'S MOTION TO STRIKE MALLINCKRODT'S  
OBJECTIONS TO SUBPOENAS**

Defendants Mallinckrodt ARD, Inc. and Mallinckrodt plc (collectively, "Mallinckrodt"), by and through their undersigned counsel, hereby file their opposition to Plaintiff's Motion to Strike Mallinckrodt's Objections to Subpoenas ("Motion").

1. Admitted in part, denied in part. Mallinckrodt admits that physicians prescribe Acthar. Mallinckrodt does not have information sufficient to state whether the physicians to whom Plaintiff seeks to send document requests are treating physicians of Plaintiff's beneficiaries. Mallinckrodt denies the remainder of the paragraph. By way of further response, Mallinckrodt incorporates its accompanying Memorandum in Support of its Opposition to Plaintiff's Motion to Strike Mallinckrodt's Objections to Subpoenas ("Memorandum").
2. Admitted in part, denied in part. Mallinckrodt admits that on July 11, 2019, Plaintiff

provided notice to Mallinckrodt's counsel of its intention to serve subpoenas on Dr. Irene Greenhouse, M.D., Dr. Gary W. Clauser, M.D., and Dr. Steven Urbaniak, D.O. ("the Physicians") and that the subpoenas ("Subpoenas") are attached to the Motion to Strike as Exhibit A to Plaintiff's Motion. Mallinckrodt denies the remainder of the paragraph. To the extent that Paragraph 2 purports to characterize a Court order, the order speaks for itself and no response is required. By way of further response, Mallinckrodt incorporates its accompanying Memorandum.

3. Admitted in part, denied in part. Mallinckrodt admits that the Subpoenas included 17 document requests but denies that they were specific or relevant to the claims in Plaintiff's Amended Complaint ("Complaint"). By way of further response, Mallinckrodt incorporates its accompanying Memorandum.

4. Denied. By way of further response, Mallinckrodt incorporates its accompanying Memorandum.

5. Admitted in part, denied in part. Mallinckrodt admits that it objected to the Subpoenas and that one of its many objections was that the Subpoenas "are beyond the scope of permissible discovery." Mallinckrodt denies the remainder of the paragraph. By way of further response, Mallinckrodt incorporates its accompanying Memorandum.

6. Denied. Mallinckrodt denies that its objections to the Subpoenas are premature or improper, as they were made in accordance with Pennsylvania Rules of Civil Procedure 4009.21(c). Mallinckrodt denies the remainder of the paragraph. By way of further response, Mallinckrodt incorporates its accompanying Memorandum.

7. Denied. Paragraph 7 is a legal argument to which no response is required. To the extent a response is required, Mallinckrodt denies the remaining allegations in Paragraph 7. By way of further response, Mallinckrodt incorporates its accompanying Memorandum.

8. Denied. By way of further response, Mallinckrodt incorporates its accompanying Memorandum.

9. Admitted in part, denied in part. Mallinckrodt admits that Mallinckrodt's counsel spoke with Plaintiff's counsel regarding Mallinckrodt's objections to the Subpoenas and that Ryan Watts, counsel for Mallinckrodt, sent a letter to William Platt, counsel for Plaintiff, dated October 2, 2019. Mallinckrodt denies the remainder of the paragraph. By way of further response, Mallinckrodt incorporates its accompanying Memorandum.

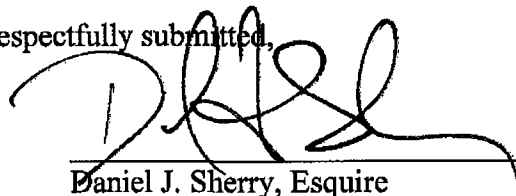
10. Denied. To the extent that Paragraph 10 purports to quote from the Complaint, the document speaks for itself and no response is required. Mallinckrodt denies the remainder of Paragraph 10. By way of further response, Mallinckrodt incorporates its accompanying Memorandum.

11. Denied. By way of further response, Mallinckrodt incorporates its accompanying Memorandum.

**WHEREFORE**, based on the responses above and the arguments presented in the Memorandum, Mallinckrodt respectfully requests that the Court deny Plaintiff's Motion.

Dated: October 18, 2019

Respectfully submitted,



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and Mallinckrodt plcINTERNATIONAL UNION OF OPERATING : IN THE MONTGOMERY COUNTY  
ENGINEERS LOCAL 542 : COURT OF COMMON PLEAS

v. :

MALLINCKRODT ARD, INC., formerly :  
known as QUESTCOR :  
PHARMACEUTICALS, INC. :

No. 2018-14059

MALINCKRODT PLC :

EXPRESS SCRIPTS HOLDING COMPANY :

EXPRESS SCRIPTS, INC. :  
CURASCRIPT, INC. :

CURASCRIPT SD :

ACCREDITO HEALTH GROUP, INC. :

and :

UNITED BIOSOURCE CORPORATION, now :  
known as UNITED BIOSOURCE LLC., a :  
wholly owned subsidiary of UNITED :  
BIOSOURCE HOLDINGS, INC. :**CERTIFICATE OF SERVICE**

Daniel J. Sherry, Esquire hereby certifies that a true and correct copy of the foregoing Defendant Mallinckrodt ARD, Inc.'s Opposition To Plaintiff's Motion To Strike Defendant Mallinckrodt ARD, Inc.'s Objections To Subpoenas was electronically filed and forwarded to the following via email and/or United States First Class Mail, postage prepaid, on the 18<sup>th</sup> day of

October, 2019:

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By: 

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# EXHIBIT 1

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**IN THE COURT OF COMMON PLEAS  
FOR MONTGOMERY COUNTY, PENNSYLVANIA**

**INTERNATIONAL UNION OF OPERATING  
ENGINEERS LOCAL 542**

1375 Virginia Drive, Suite 102

Fort Washington, PA 19034

Plaintiff

v.

**MALLINCKRODT ARD, INC.**

*formally known as*

**QUESTCOR PHARMACEUTICALS, INC.**

675 McDonnell Blvd.

Hazelwood, MO 63042

**MALLINCKRODT PLC**

3 Lotus Park, the Causeway

Staines-upon-Thames,

Surrey, TW18 3 AG

**EXPRESS SCRIPTS HOLDING COMPANY**

1 Express Way

St. Louis, MO 63121

**EXPRESS SCRIPTS, INC.**

1 Express Way

St. Louis, MO 63121

**Civil Action No.: 2018-14059**

**JURY TRIAL DEMANDED**

**CURASCRIP, INC.**  
6272 Lee Vista Boulevard  
Orlando, FL 32822

**CURASCRIP SD**  
255 Technology Park  
Lake Mary, FL 32746

**ACCREDITO HEALTH GROUP, INC.**  
1640 Century Center Parkway  
Memphis, TN 38134

*and*

**UNITED BIOSOURCE CORPORATION,  
now known as UNITED BIOSOURCE LLC,  
a wholly owned subsidiary of UNITED  
BIOSOURCE HOLDINGS, INC.**  
920 Harvest Drive  
Blue Bell, PA 19422

Defendants.

**NOTICE TO DEFEND**

You have been sued in Court. If you wish to defend against the claims set forth in the following pages, you must take action within twenty (20) days after this complaint and notice are served, by entering a written appearance personally or by attorney and filing in writing with the court your defenses or objections to the claims set forth against you. You are warned that if you fail to do so the case may proceed without you and a judgment may be entered against you by the court without further notice for any money claimed in the complaint or for any other claim or relief requested by the plaintiff. You may lose money or property or other rights important to you.

YOU SHOULD TAKE THIS PAPER TO YOUR LAWYER AT ONCE. IF YOU DO NOT HAVE A LAWYER, GO TO OR TELEPHONE THE OFFICE SET FORTH BELOW. THIS OFFICE CAN PROVIDE YOU WITH INFORMATION ABOUT HIRING A LAWYER.

IF YOU CANNOT AFFORD TO HIRE A LAWYER, THIS OFFICE MAY BE ABLE TO PROVIDE YOU WITH INFORMATION ABOUT AGENCIES THAT MAY OFFER LEGAL SERVICES TO ELIGIBLE PERSONS AT A REDUCED FEE OR NO FEE.

LAWYER REFERENCE SERVICE  
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**AMENDED  
CIVIL ACTION COMPLAINT**

Plaintiff, International Union of Operating Engineers Local 542 (“IUOE Local 542”, or “Plaintiff”), by and through its undersigned counsel, alleges as follows:

1. IUOE Local 542 brings this action to challenge an unjust, unfair, deceptive, and anti-competitive scheme by Defendants Mallinckrodt ARD Inc., formally known as Questcor Pharmaceuticals, Inc. (“Questcor”) and its parent company, Mallinckrodt plc (collectively “Mallinckrodt”), along with Mallinckrodt’s exclusive agent for the delivery of its products Express Scripts Holding Company and Express Scripts, Inc. (together referred to as “ESI”), including their three (3) wholly-owned subsidiaries: CuraScript, Inc. and CuraScript, SD. (“CuraScript”), Accredo Health Group, Inc. (“Accredo”) and United BioSource Corporation, now known as United BioSource LLC, a wholly owned subsidiary of United BioSource Holdings, Inc. (“UBC”)(collectively referred to as “Express Scripts”).

2. Mallinckrodt manufactures, markets, distributes and sells H.P. Acthar, NDC Nos. 63004-8710-01 and 63004-7731-01 (“Acthar”). Acthar is the only therapeutic adrenocorticotrophic hormone (“ACTH”) product sold in the United States. Mallinckrodt is the sole provider in the United States of approved ACTH drugs. Thus, Mallinckrodt is a monopolist.

3. Mallinckrodt acquired its Acthar monopoly in 2001 when Questcor purchased Acthar from Aventis for \$100,000. By 2014, when Mallinckrodt purchased Questcor, the value of that Acthar monopoly was \$5.9 billion—the price paid for the single-product company. This stark increase in value was not due to any change in the Acthar being sold. The formulation of the drug has never changed. The only change between 2001 and 2014 was the price.

4. This case does not seek to challenge the lawfulness of Mallinckrodt’s monopoly. It seeks to challenge the lawfulness of Mallinckrodt’s exercise of its monopoly power by taking

actions to maintain and enhance that monopoly power in violation of Pennsylvania law that prescribes such conduct.

5. The issue is also not whether Mallinckrodt possessed monopoly power for Acthar. It is whether Mallinckrodt's actions in contracting with the largest agent of its leading customers, Express Scripts, and in acquiring the only competitive product in the marketplace, Synacthen, constitute unfair and deceptive acts or practices under Pennsylvania law. As described below, the Federal Trade Commission ("FTC") and a competitor of Mallinckrodt both charged the company with antitrust, which Mallinckrodt chose to settle rather than fight. The actions and omissions underlying these charges of antitrust by the FTC form part of the bases of the unlawful conduct charged in this Complaint under Pennsylvania law.

6. In this case, brought exclusively under Pennsylvania state law, Plaintiff alleges that the Defendants engaged in unfair and deceptive conduct by intentionally and artificially inflating the costs of Mallinckrodt's Acthar, which Plaintiff paid for under a contract with Express Scripts, and by concealing from IUOE Local 542 the true costs for Acthar through undisclosed, direct contractual arrangements between Mallinckrodt and Express Scripts. In charging inflated prices for Acthar, and collecting the money from Plaintiff for such prices, Defendants concealed their direct relationships and deceived Plaintiff as to Express Scripts' role in the distribution, pricing and sale of Acthar to IUOE Local 542 beneficiaries. Plaintiff made direct payments of these inflated prices to Express Scripts, for the benefit of Mallinckrodt, thereby unjustly enriching both Defendants.

7. Acthar is a "specialty pharmaceutical". Unlike most prescription drugs, it is not sold in retail pharmacies, nor is it distributed through wholesalers to retail pharmacies. Instead, it is distributed only through "specialty pharmacy distributors" ("SPDs") and "specialty

pharmacy providers” (“SPPs”).

8. One of the largest SPDs in America is ESI’s CuraScript, which ESI has owned since 2004.

9. In 2007, Mallinckrodt decided to embark on a “new strategy” and it changed its distribution of Acthar. Rather than continue to distribute Acthar to the existing distribution network available for specialty drugs, Mallinckrodt decided to limit Acthar distribution exclusively through ESI’s CuraScript. In effect, Mallinckrodt contracted with the agent of its leading customers, including IUOE Local 542, and the largest SPD at the time, in order to create an exclusive arrangement whereby both companies would share the financial rewards of the Acthar monopoly through exorbitantly higher prices. Defendants concealed this exclusive arrangement from Plaintiff with the intention to deceive Plaintiff as to the real reason for Acthar price increases which followed.

10. Immediately after agreeing to the exclusive arrangement, Mallinckrodt and Express Scripts agreed to raise the price of Acthar from about \$2,062.79 per vial of 80 units/ml, 5ml before August 2007 to about \$29,086.25 per vial thereafter. As a result, Mallinckrodt was able to charge inflated prices for Acthar to Express Scripts’ clients, including IUOE Local 542. There had been no change in any cost of Acthar to the Defendants, in the terms of costs of manufacture, distribution or sale. Thus, the Defendants’ misrepresented the true prices of Acthar, which prices Plaintiff relied upon in paying them.

11. IUOE Local 542 has spent approximately \$153,775.95 for just 5 administrations of Acthar given to 3 separate adult patients. The new prices of these administrations, as relied upon and paid for by IUOE Local 542, were as follows: \$26,095.28 on July 5, 2011 for 1 patient, \$60,846.04 on March 13, 2013 for 2 administrations to a second patient, and \$32,180.68 on July

29, 2014 and \$34,653.95 on July 9, 2015 for separate administrations to a third patient. When Mallinckrodt acquired the Acthar monopoly from Aventis, the cost of an individual vial was just \$40.00. Just prior to Mallinckrodt's undisclosed exclusive agreement with Express Scripts and CuraScript, the cost of an individual Acthar vial was around \$2,000. IOUE Local 542 thus paid more for Acthar than it otherwise would have paid in the absence of Defendants' misrepresentations and deception about Acthar pricing, and conspiracy between Mallinckrodt and Express Scripts to maintain and enhance Mallinckrodt's monopoly power, allowing it to charge exorbitant prices. The precise amount of IOUE Local 542's damages will be determined after discovery.

12. For this reason, IOUE Local 542 brings this case to obtain declaratory and injunctive relief and to recover monetary damages. IOUE Local 542 sues all Defendants for violations of Pennsylvania's consumer fraud laws, negligent misrepresentation, unjust enrichment and aiding and abetting. IOUE Local 542 also sues Express Scripts for breach of contract, promissory estoppel and breach of the duty of good faith and fair dealing. Plaintiff seeks declaratory and injunctive relief against all Defendants.

### **JURISDICTION AND VENUE**

13. IOUE Local 542 brings this action pursuant to the consumer protection laws of Pennsylvania, as well as the common law of Pennsylvania. No aspect of the claims asserted in this Complaint is brought pursuant to any federal law, including, but not limited to, RICO, the Sherman Act, or the Clayton Act, and thus no federal question is raised by any of Plaintiff's claims asserted. The mention of Mallinckrodt's violations of antitrust laws is only intended to describe the fact the company has been sued by both the FTC and Retrophin in related lawsuits for the same conduct, which lawsuits the company settled, and to distinguish the claims asserted

in this state case from those asserted by other plaintiffs in federal court. To the extent any of Plaintiff's claims or factual allegations herein may be construed to have stated any claim under federal law, such claim is expressly and undeniably disavowed and disclaimed by Plaintiff. Moreover, to the extent any of Plaintiff's claims or factual allegations herein are urged by any of the Defendants to have stated any claim under federal law, Plaintiff expressly disavows such claims or allegations and reserves the right to modify this Complaint to conform its claims.

14. This Court has personal jurisdiction over Plaintiff and its members and beneficiaries because they reside in Pennsylvania and have purchased and reimbursed for Acthar and other drugs within the Commonwealth of Pennsylvania.

15. This Court has jurisdiction over the Defendants because they are present and/or conduct substantial business in this Commonwealth, have registered to conduct business here, have had systematic and continuous contacts with this Commonwealth, and/or have agents and representatives that can be found in this Commonwealth.

16. The Court has jurisdiction over the Defendants because they have had sufficient minimum contacts with and/or have purposefully availed themselves of the laws and markets of the Commonwealth of Pennsylvania through, among other things, their distribution, marketing and sales of Acthar to IUOE Local 542 and other residents of Pennsylvania.

17. Furthermore, by the Express Scripts, Inc. Pharmacy Benefit Management Agreement (hereinafter the "ESI PBM Agreement") at issue here, Express Scripts and IUOE Local 542 agreed that the ESI PBM Agreement "will be construed and governed in all respects according to the laws in the Commonwealth of Pennsylvania, without regard to the rules of conflict of laws thereof".

18. Venue is proper in this County because Plaintiff and Defendant UBC are situated

in this County, and the other Defendants transact business in this County. Venue is also proper because a substantial part of the events giving rise to the Plaintiff's claims occurred in this County. Defendants engaged in substantial conduct relevant to the Plaintiff's claims and caused harm to Plaintiff in Montgomery County, Pennsylvania.

## **THE PARTIES**

### **PLAINTIFF**

19. IUOE Local 542 is a Taft-Hartley union fund providing health and welfare benefits to its members and their families. IUOE Local 542 resides at 1375 Virginia Drive, Suite 100, Fort Washington, PA 19034, which is situated in Montgomery County, Pennsylvania.

20. IUOE Local 542 has represented the interests of working men and women in Eastern Pennsylvania since 1935, including heavy equipment operators in the building and construction industry, along with C & D-Branch Division members who are employed at quarries, landfills, equipment dealers, shipyards, breweries, manufacturing plants, airports, bridges, and public works.

21. Three such members of IUOE Local 542 had serious medical conditions, for which Acthar was indicated as a treatment option. These members of IUOE Local 542 received Acthar directly from Mallinckrodt's authorized agent, Express Scripts. IUOE Local 542, which pays the health care benefits of its members, including specialty pharmacy drugs, then paid for these administrations of Acthar.

22. The sum total of the 4 prescriptions (5 administrations) paid for by IUOE Local 542 was \$153,775.95. The administrations were given to the below 3 adult patients on the listed dates, for which IUOE paid the listed amounts based on the Average Wholesale Price ("AWP") as established by Defendants:

Patient	NDC	Date Filled	AWP	Billed Amount	Co-Pay
Patient 1	63004-7731-01	2011/07/01	\$30,783.60	\$26,095.28	\$40.00
Patient 2	63004-8710-01	2013/03/13	\$71,715.00	\$60,846.04	\$40.00
Patient 3	63004-8710-01	2014/07/29	\$37,951.20	\$32,180.68	\$40.00
Patient 3	63004-8710-01	2015/07/09	\$40,840.80	\$34,653.95	\$20.00

23. IUOE Local 542 paid \$153,775.95 directly to Express Scripts, as agent for Mallinckrodt. These monies were then transferred by Express Scripts to Mallinckrodt, after Express Scripts deducted its undisclosed (to Plaintiff), but agreed-upon (with Mallinckrodt), share of the revenues.

#### DEFENDANTS

24. Questcor Pharmaceuticals, Inc. (“Questcor”) was acquired by Mallinckrodt on August 14, 2014 for \$5.9 billion, after paying only \$100,000 for Questcor’s lone product 13 years earlier. Following the acquisition, Questcor became a wholly-owned subsidiary of Mallinckrodt and its name was changed to Mallinckrodt ARD Inc. Mallinckrodt ARD is a biopharmaceutical company incorporated in California, with offices located at 675 McDonnell Boulevard, Hazelwood, Missouri 63042. Mallinckrodt ARD now has locations in Hampton, New Jersey and Bedminster, New Jersey. For clarity, where necessary, the entity that existed prior to the Mallinckrodt acquisition is herein referred to as “Questcor”.

25. At the time of the Mallinckrodt acquisition, Questcor’s only product sold in the United States was Acthar. As of the date of this Complaint, Mallinckrodt continues to manufacture, distribute and sell Acthar directly to patients, exclusively through Express Scripts, by a program known as the “Acthar Support and Access Program” (“ASAP”) described below.

26. Defendant, Mallinckrodt plc (“Mallinckrodt plc”), is an Irish public limited company, with its corporate headquarters in Staines-upon-Thames, United Kingdom. Its principal executive offices are located at 3 Lotus Park, the Causeway, Staines-upon-Thames, Surrey, TW18 3 AG.

27. Mallinckrodt plc, Mallinckrodt ARD and Questcor are collectively referred to as “Mallinckrodt”.

28. Defendants Express Scripts, Inc. and Express Scripts Holding Company are Delaware Corporations with their principle executive offices located at 1 Express Way, Saint Louis, Missouri 63121. Together, Express Scripts, Inc. and Express Scripts Holding Company are referred to as “ESI”.

29. Defendant CuraScript, Inc. is a Delaware corporation with its principal place of business at 6276 Lee Vista Blvd., Orlando, FL 32822, and is a wholly-owned subsidiary of ESI. CuraScript, Inc. was acquired by ESI in January 2004. CuraScript, Inc. operates as an SPP.

30. In October 2005, Express Scripts acquired the capital stock of Priority Healthcare Corporation (“Priority”) for \$1.3 billion. The acquisition was accomplished through the merger of wholly-owned CuraScript, Inc. with and into Priority. Priority is headquartered at 255 Technology Park, Lake Mary, Florida. Since the acquisition, Priority has done business as Priority Healthcare Distribution, Inc. d/b/a CuraScript SD Specialty Distribution (“CuraScript SD”). (CuraScript, Inc. and CuraScript SD are collectively referred to as “CuraScript”.) The combined Priority and CuraScript became one of the nation’s largest specialty pharmacy and distribution companies with more than \$3 billion in annual revenue.

31. CuraScript SD’s corporate headquarters are now located at 255 Technology Park, Lake Mary, Florida 32746, the address of Priority. This is the same address patients are required



to mail any revocation of the broad authorization granted by patients to Mallinckrodt and UBC via the Acthar Start Form (*see*, Exhibit “A” hereto). CuraScript is Mallinckrodt’s exclusive SPD for Acthar.

32. Defendant Accredo Health Group, Inc. (“Accredo”) is a wholly-owned subsidiary of ESI. Accredo became a wholly-owned subsidiary of Medco Health Solutions, Inc. (“Medco”) on August 18, 2005, months before ESI acquired Priority, and then became part of ESI when ESI acquired Medco in April 2012.

33. Accredo is a Delaware corporation with its corporate headquarters at 1640 Century Center Parkway, Memphis, Tennessee 38134. Accredo also has operations in Warrendale, Pennsylvania, Corona, California, Greensboro, North Carolina, Orlando, Florida, Indianapolis, Indiana, and Nashville, Tennessee.

34. Defendant United BioSource Corporation (“UBC”) is a Delaware corporation with its corporate headquarters at 920 Harvest Drive, Blue Bell, Pennsylvania 19422. UBC was a wholly-owned subsidiary of ESI. UBC was acquired by ESI in 2012 as part of the Medco merger.

35. On November 27, 2017, ESI announced that it sold UBC to Avista Capital Partners, a private equity firm. UBC is now known as United BioSource LLC, a wholly-owned subsidiary of United BioSource Holdings, Inc.

36. UBC is described as Mallinckrodt’s “agent” on the Acthar Start Form (Exhibit “A” hereto) which Mallinckrodt employs exclusively to operate the ASAP program and to manage ESI’s exclusive distribution, sales and reimbursement of Acthar by its 3 operating arms, CuraScript, Accredo and ESI.

37. As stated in Paragraph 1, ESI, CuraScript, Accredo and UBC are collectively referred to herein as “Express Scripts”.

38. Mallinckrodt and Express Scripts are collectively referred to herein as “Defendants”, as appropriate.

39. The Defendants’ acts alleged in this Complaint to have been done by each of the Defendants were authorized, ordered, done and/or ratified by their respective officers, directors, agents, employees or representatives while engaged in the management, direction, control or transaction of their respective business affairs.

### **FACTUAL BACKGROUND**

40. “I have a Cadillac in my refrigerator.” That is how one Acthar patient named Sharon Keller described an unused 5-ml vial of the medication sitting in her kitchen refrigerator.

41. The tale of how a 65-year-old brand medication could rise in price from \$40 per vial in 2001 to \$40,840.80 per vial by 2015, raising that value of the brand from \$100,000 to \$5.9 billion, is a story of perhaps the most egregious fraud and monopolistic conduct by a prescription drug company in United States history.

#### **History of Acthar Development, Distribution and Pricing**

42. Acthar was approved by the Food and Drug Administration (“FDA”) in 1952 for over fifty conditions, ranging from alcoholism, poison ivy, and radiation sickness to nephrotic syndrome. Over time, with additional evidence-based requirements for prescription drugs, the list was reduced to the present-day nineteen indications.

43. Acthar is adrenocorticotrophic hormone (“ACTH”), which causes the body to produce cortisone and other steroid hormones. Two Mayo Clinic researchers, Drs. Philip Hench and Edward Kendall, developed the treatment, which won them the Nobel Prize for medicine at

the time it was developed. Acthar was developed by Armour Pharmaceutical Company. As described by the Seventh Circuit in *Armour & Co. v. Wilson & Co.*, 274 F.2d 143, 145-46 (7th Cir. 1960):

In a human being, . . . (ACTH) appears in the anterior lobe of the pituitary gland located at the base of the brain. When the human body is under stress or attacked by certain diseases, control centers in the brain excite the pituitary, and the pituitary secretes ACTH. In the blood stream the ACTH thus secreted is carried to the adrenal glands situated in the human body above the kidneys. As the ACTH hits the outer wall of the adrenal glands, it stimulates the adrenals to produce a set of chemical substances such as steroids, including the hormones, cortisone and hydrocortisone.

The cortisone hormones then act in the tissues of the body to suppress inflammations and allergic reactions. ACTH thus is used to relieve such conditions as rheumatoid arthritis and allergies. ACTH does not, itself, directly attack disease. However, it stimulates the adrenals which produce more than twenty-eight steroids, and these hormones attack the diseased tissues. When the human body itself does not supply sufficient ACTH, pharmaceutical ACTH can fill the gap.

44. By the 1960s, injectable ACTH medications faced a variety of competing products. *See id.* at 145 (“Both Armour and Wilson manufacture and sell gelatin-ACTH preparations ... Gelatin-ACTH now constitutes more than 80% [o]f all forms of ACTH products sold by Armour and Wilson. Other companies ... produce similar products”).

45. For the majority of the drug’s lifespan, however, generic corticosteroids, such as prednisone, effectively treated the majority of the indications for which Acthar was approved. That factor tended to limit the market for Acthar to treating infantile spasms (“IS”) which was originally an “off-label” indication. Consequently, because of the limited, off-label market for Acthar, by 2001, the drug was priced at \$40 per vial and accounted for less than a million dollars of revenue for Aventis Pharmaceuticals, Inc. (“Aventis”), the then-owner.

46. In 2001, Questcor acquired Acthar from Aventis for only \$100,000, but in 2014 Mallinckrodt acquired Questcor for \$5.9 billion.

47. Acthar's value was limited because it was the "gold standard" for treating only one condition, infantile spasms ("IS"). IS is a serious condition in infants, but one with an annual patient population of less than 2,000 children per year. However, Acthar was not originally approved by the FDA to treat IS, further limiting its value. A few years later, the IS indication was approved by the FDA.

**Mallinckrodt Adopts a "New Strategy" to Restrict Acthar Distribution to Maintain and Enhance its Monopoly Power over Acthar Through a Misleading and Deceptive Arrangement with Express Scripts.**

48. Acthar is a specialty pharmaceutical distributed directly to patients, like the IUOE Local 542 beneficiaries in this case.

49. For decades, Acthar was distributed to any doctor, hospital, wholesaler or specialty pharmacy who requested the drug to treat seriously ill patients. After Questcor acquired the rights to Acthar, it maintained that broad distribution network.

50. However, on July 2, 2007, Mallinckrodt restricted its distribution from three wholesalers, termed Wholesalers "A", "B", and "C" in its 2007 10-K, to just Express Scripts, the agent of its largest customers. Mallinckrodt did not tell IUOE Local 542 or the public the truth about its exclusive arrangement. Instead, Mallinckrodt's July 2, 2007 announcement stated, **"[e]ffective August 1, 2001, Acthar...will be available exclusively through Specialty Pharmacy Distribution.** Acthar Gel will no longer be available from traditional pharmaceutical wholesalers or retail pharmacies." See July 2, 2007, "Urgent Product Alert H.P. Acthar Gel" at Exhibit "B" hereto. All distribution would now be done exclusively through CuraScript via the Acthar Support & Access Program ("ASAP"). "[A]ll new Acthar Gel prescriptions should be

submitted to the Acthar Support & Access Program.” *Id.* However, Mallinckrodt’s announcement failed to disclose that all aspects of Acthar distribution and sales were now being handled by Express Scripts, including managing the ASAP Program, and that the Defendants had agreed between themselves to raise the prices for Acthar.

51. The goal of this “new strategy” was to deceive patients and payors in order to lock them into receiving Acthar through one distribution channel controlled by Mallinckrodt and Express Scripts, and to ensure prescription distribution, pricing and payment went through one source, Express Scripts. That way, Mallinckrodt could bypass specialty pricing controls IUOE Local 542 put in place. Mallinckrodt has maintained this exclusive arrangement with Express Scripts since 2007, and up and through the years Plaintiff paid for Acthar, 2014-2015.

52. Mallinckrodt manages its exclusive arrangement with Express Scripts through the ASAP program. ASAP is structured so that Mallinckrodt ships Acthar directly to patients and receives payment directly from the associated third-party payors, including Plaintiff.

53. Once the patient (or their physician) contacts Mallinckrodt for a prescription of Acthar, they are directed to UBC. Otherwise, patients and/or their providers contact UBC directly, as directed by the Acthar Start Form which is attached as Exhibit “A”. UBC then serves as the self-described “hub” for Mallinckrodt and Express Scripts’ exclusive arrangement. It confirms the patient’s insurance coverage or other source of payment, and then arranges for Acthar to be delivered directly to the patient by CuraScript.

54. The process, which is laid out in Mallinckrodt’s Acthar Start Form, requires patient, physician and payor authorization before Mallinckrodt agrees to ship Acthar to patients via ESI/CuraScript. *See* Exhibit “A” hereto. Thus, Express Scripts is not at risk. The Acthar Start Form consists of 3 sections: (1) a section requiring signature by the “HCP” (or health care

professional); (2) a patient authorization requiring signature by the “patient or legal representative”; and (3) an information form concerning Acthar indications and usage. The required signature of the patient authorizes “Mallinckrodt and its agents” to do a number of things in relation to the prescription and distribution of Acthar. It further authorizes Mallinckrodt and its agents, “including Mallinckrodt reimbursement support personnel and United BioSource Corporation (“UBC”) or any other operator of the Acthar Support Access Program on behalf of Mallinckrodt (collectively, ‘Designated Parties’)” to provide Acthar and receive payment, among other things.

55. Specifically, the patient authorizes Mallinckrodt, UBC, “or any other operator” of ASAP on behalf of Mallinckrodt, “collectively (‘Designated Parties’), to provide certain services to [the patient], including reimbursement and coverage support, patient assistance and access programs, medication shipment tracking, and home injecting training.” In other words, the patient directly authorizes Mallinckrodt and its agents to ship Acthar to them directly via CuraScript, and authorizes payment by both the patient and any third party payor prior to obtaining the medication. The patient therefore authorizes Express Scripts to bill the payor, such as IUOE Local 542, for Acthar. Ex. “A”.

56. Similarly, the physician must “authorize[ ] United BioSource Corporation (UBC), the current operator of the Acthar Support and Access Program (Program), and other designated operators of the program, to perform a preliminary assessment of benefit verification for this patient...”. The physician also “agree(s) that the designated specialty pharmacy receive this prescription via a designated third party, the Program and that no additional confirmation of receipt of prescription is required by the designated specialty pharmacy.” Exhibit “A” hereto.

57. The interaction of all 4 elements of Express Scripts' functions on behalf of Mallinckrodt is described below.

58. Express Scripts is the largest buyers' agent for pharmaceuticals in the United States. Express Scripts has substantial buying power as a result of its representation of the largest number of buyers in the pharmaceutical marketplace.

59. Express Scripts styles itself as a "pharmacy benefit manager" or "PBM", but it does more than simply process claims for prescriptions filled at retail pharmacies. In addition to "retail pharmacy claims processing, formulary management, utilization management and home delivery pharmacy services", Express Scripts offers "specialty services that deliver ... high-cost injectable, infused, oral or inhaled drugs," and "compliance programs, ... drug therapy management programs, [] data analysis, and [] distribution services."<sup>1</sup> Acting "either directly or through its subsidiaries", Express Scripts acts as a direct pipeline from a pharmaceutical manufacturer to the patient, facilitating the direct distribution of prescription drugs from the factory to the patient's home.

60. Express Scripts acts as a manufacturer's direct distributor of specialty drugs to patients because it provides what it calls "integrated specialty services." (emphasis in original).<sup>2</sup> As one Express Scripts executive put it, "we're family." These integrated services include the PBM (ESI), the SPD (CuraScript) and the SPP (Accredo).

61. Express Scripts coordinates all of these functions through its so-called pharmaceutical support services unit, UBC. UBC acts as a " 'hub,' that serves as a centralized

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<sup>1</sup> Express Scripts Holding Company Annual Report on Form 10-K for the Fiscal Year Ending December 31, 2012.

<sup>2</sup> <https://curascriptsd.com/corporate-overview>

point of contact for [] patients [] and prescribers”<sup>3</sup> by “[w]orking hand-in-hand with Express Scripts’ specialty pharmacy and specialty distribution organizations, Accredo and CuraScript [],”<sup>4</sup> to coordinate delivery of and reimbursement for specialty pharmaceuticals.

62. In total, UBC operates “an integrated service model that involves UBC . . . manag[ing] multiple system applications that support one product. [UBC’s] services include the UBC coordinating center, nurse coordination . . . product fulfillment through Accredo and wholesale fulfillment through CuraScript[]. When a patient is prescribed [a specialty] medication, the doctor sends a referral to the Reimbursement Hub. [UBC’s] team serves as the liaison among doctors, patients and insurance companies as [UBC]...navigates[s] the coverage process. [UBC]...ensure[s] a smooth transition from enrollment through shipment of the medication.”

63. Part of the reimbursement hub process is coordination with Express Scripts’ CuraScript, which acts as an “integrated delivery network” connecting patients to manufacturers through “end-to-end distribution services.”<sup>5</sup> Simply put, CuraScript is similar to a FedEx, DHL, or UPS for specialty prescription drugs. CuraScript advertises that it is “recognized by the manufacturing community as [] a reliable partner in the management of brands” through CuraScript’s “integrated specialty services,” which deliver medications to patients “alongside sister organizations Accredo and UBC.”<sup>6</sup>

64. To facilitate these end-to-end distribution services, UBC coordinates CuraScript’s activities with Accredo, which provides so-called specialty pharmacy services.

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<sup>3</sup> <http://www.ubc.com/services/loyalty/reimbursement-patient-assistance>

<sup>4</sup> <http://www.ubc.com/services/loyalty/reimbursement-patient-assistance>

<sup>5</sup> <https://curascriptsd.com/Rare-Disease-Specialty-Distribution-Program>

<sup>6</sup> <https://curascriptsd.com/supplier-relations>



65. But, this integration including the financial relationship and incentives created thereby, is not fully disclosed by Express Scripts. By acting as the hub, UBC ensures that a patient whose pharmacy benefits are managed by ESI can get a specialty medication delivered to him or her by coordinating shipment through CuraScript and Accredo and payment through ESI. “As one UBC executive has explained “if UBC is the Hub and Accredo is the [specialty pharmacy] . . . we can send the patient’s prescription over to Accredo, and they will not have to duplicate any of our efforts, which another pharmacy would be compelled to do because of risk. Accredo trusts us.”

66. Accredo provides specialty pharmacy and related services for patients with certain complex and chronic health conditions. Accredo’s staff is comprised of a team of specialty-trained pharmacists, nurses, patient care advocates, social workers and insurance coordinators whom, among other things, “handle everything about” a patients’ medications and/or specialty therapy.

67. Along with UBC, Accredo provides: (a) support to orphan and ultra orphan patient populations; (b) HUB employees to navigate insurance requirements, like prior authorizations, for patients and prescribers; (c) clinicians who are available 24/7 to address patient concerns and provide guidance on mitigating adverse events; (d) reimbursement HUB specialists to steer patients to funding solutions, and (e) an integrated solution allowing patients to start therapy twice as fast.

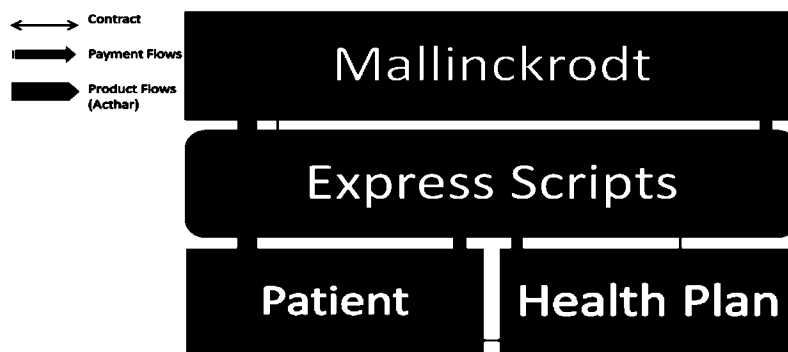
68. Accredo publicly represents that by using Accredo’s specialty pharmacy services, plan sponsors like IUOE Local 542 can save money by managing their specialty spend through Accredo. Accredo further promises patients the most effective and affordable medications while ensuring appropriate utilization, managing unit costs, driving out waste, and reducing related

medical expenses. In reality, however, the use of Accredo only insured that IUOE Local 542 would pay the inflated prices for Acthar that Express Scripts agreed with Mallinckrodt to charge.

69. In simple terms, through UBC's coordination with Accredo, CuraScript, and ESI, Express Scripts delivers a prescription drug directly from the manufacturer to the patient, bypassing all impediments to delivery and payment, whether medical, logistical or financial. The most important impediment is the leverage of Express Scripts, as agent for IUOE Local 542 in negotiating with prescription drug companies, like Mallinckrodt, for lower prices.

70. With respect to Acthar, Mallinckrodt has a contract with UBC to coordinate the delivery of Acthar through the ASAP Program. Beginning with its July 2, 2007 announcement, Mallinckrodt directed physicians to prescribe Acthar through the ASAP program. *See* Exhibit "B". In this announcement, Mallinckrodt directed physicians that "all new Acthar [] prescriptions should be submitted to the [ASAP program]." Prescriptions are submitted to the ASAP program through the "Acthar Start Form." *See* Exhibit "A". This form authorizes UBC to coordinate reimbursement with ESI and direct the prescription to a "designated specialty pharmacy." This designated specialty pharmacy is Accredo. Accredo dealt with Local 542's patient members. Part of UBC's activities involve coordinating the shipment of Acthar from CuraScript through Accredo to the patient. Indeed, in order to revoke UBC's authorization to perform these services, the patient must mail a letter to CuraScript's address in Florida.

71. The Acthar distribution arrangement between Express Scripts and Mallinckrodt is illustrated in the following two figures. In Figure 1, the distribution arrangement is described in aggregate.



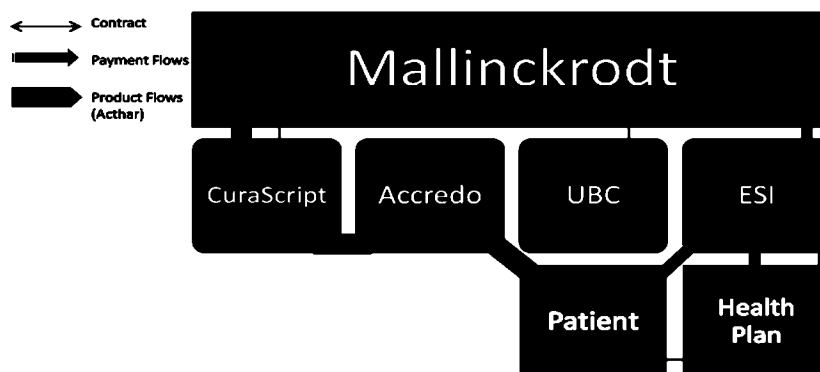
**Figure 1**

72. Figure 2, below, illustrates how Acthar is prescribed, authorized, distributed and paid for through Express Scripts. Payment flows are represented by green arrows traveling from payor and patient to Mallinckrodt, while product flows are represented by black chevrons flowing from Mallinckrodt to the patient. Although these pass through Express Scripts, payment flows and product flows are ultimately aligned between Mallinckrodt and UBC, Express Scripts' reimbursement hub, through a contract with Mallinckrodt to operate the ASAP program, which ostensibly operates to confirm the medical necessity of the prescription (by Accredo), to arrange payment (to ESI) for shipment (from CuraScript) of Acthar to patients. Through these contractual arrangements, Acthar travels from Mallinckrodt directly to the patient.

73. The patient, on the other hand, has prescription insurance coverage through his or her health plan, such as that provided by IUOE Local 542 to its patient members. In this case, IUOE Local 542 administered the health plan that covered its 3 adult patient members. The health plan has a contract with ESI, which requires ESI to collect payments for the price of Acthar as a "specialty drug".

74. By these arrangements, the Acthar product flows directly from Mallinckrodt through Express Scripts to the patient, while the money flows directly from the patient and payor

through Express Scripts back to Mallinckrodt.



**Figure 2**

75. Wielding both the largest collection of patients in the United States and a direct shipment channel for specialty drugs, Express Scripts is in a unique position to negotiate the most competitive, discount prices for specialty drugs in the United States. This bargaining power has allowed Express Scripts to push back against attempts by pharmaceutical drug manufacturers to charge inflated prices for drugs above the actual market value of the drugs.

76. However, in this case, Mallinckrodt leveraged and enhanced its monopoly power by limiting the distribution of its sole specialty drug to just one specialty pharmacy distributor, CuraScript, and employing as its agents ESI's Accredo and UBC, along with CuraScript, to coordinate all aspects of the distribution, sales and pricing of Acthar: from prescription by the physician, to direct home delivery to the patient, to direct reimbursement by the payor of inflated prices. This allowed Mallinckrodt to raise its prices tenfold initially, and nearly double in the ensuing years, without any pushback from Express Scripts.

77. Mallinckrodt Executive Vice-President Steve Cartt admitted, “[w]e did some market research,’ . . . [t]alking to physicians and others about pricing ‘gave us some comfort that the [new] strategy would work, and physicians would continue to use the drug, and payers would

pay’ . . . ‘The reality was better than we expected.’ ” See, Milt Freudenheim, *Benefit Managers Profit by Specialty Drug Rights*, New York Times, C1, April 19, 2008 (titled, “The Middleman’s Markup” in New York Print Ed.)(hereinafter, “Freudenheim”).

**IUOE Local 542’s PBM Contract with Express Scripts**

78. IUOE Local 542 has contracted with Express Scripts to provide pharmacy benefit services, among other things, since at least 2003. During the relevant time period, IUOE Local 542 has been a member of the Delaware Valley Healthcare Coalition (“DVHCC”), which has entered into various “Umbrella Agreements” with ESI for the provision of prescription drug benefit management services. IUOE Local 542 has entered into the “Pharmacy Benefit Management Agreement” with Express Scripts (“ESI PBM Agreement”).

79. The term of the ESI PBM Agreement was for three years from the commencement date. Accordingly, on February 1, 2012, DVHCC entered into an Umbrella Agreement with ESI, which included an ESI PBM Agreement, which IUOE Local 542 agreed to. The prior agreement, signed in 2010, covered the 2011 Acthar administration at issue here. ESI and IUOE Local 542 then entered into an ESI PBM Agreement dated June 1, 2015. This agreement was then updated and amended in May 2015, and then again in February 2017.

80. Under the ESI PBM agreements, ESI agreed to provide IUOE Local 542 with pharmacy benefit management services. Principal among those services has been the containment of the costs of prescription drugs, especially brand name and specialty drugs, required by the members of IUOE Local 542 for the treatment of their medical conditions, and paid for by IUOE Local 542.

81. ESI bargained with IUOE Local 542 to serve as its exclusive specialty pharmacy provider and distributor, in order to contain and reduce IUOE Local 542’s prescription drug

costs.

82. One of the specialty medications that IUOE Local 542 contracted with ESI to supply exclusively was Mallinckrodt's Acthar Gel injection. For all years during the relevant time period, Acthar has been listed as a "specialty drug" in the ESI PBM Agreement and was identified for use to treat. Express Scripts alone determines what makes a particular drug "special" for inclusion in its "specialty product list". ESI maintains the list of specialty products and their reimbursement rates. Such rates have been determined by ESI to be based on the "average wholesale price" or AWP for the drugs. "ESI updates the list of Specialty Drugs and assigns a default AWP to each drug by therapeutic category as new drugs are brought to market."

83. The ESI PBM Agreement purports to provide IUOE Local 542 members with the opportunity to obtain Acthar "at a Participating Pharmacy", and not through CuraScript. In actuality, and for all years since 2007, Acthar has only been available through CuraScript, but ESI never disclosed such fact to IUOE Local 542. ESI also never disclosed the fact of its exclusive arrangement with Mallinckrodt beginning in 2007 and continuing through the present, and in fact misrepresented this fact in its contract with IUOE Local 542. This exclusive arrangement has caused the AWP-based prices of Acthar to increase each year, including at the exorbitant amounts described herein. In fact, ESI's "list of specialty products" attached to the ESI PBM Agreement specifically, and deceptively, lists Acthar as available at participating pharmacies for a reimbursement rate of AWP minus 12%, as opposed to through CuraScript exclusively, at a rate of AWP minus 15%. Acthar is not listed as a "limited distribution" drug, which it clearly has been since 2007.

84. IUOE Local 542 agreed to pay ESI certain reimbursement rates for specialty pharmacy drugs as established by ESI for each such drug. The reimbursement rates for each

drug varied from a discount of 0% to 54.25%. For Acthar, Mallinckrodt charged IUOE Local 542 at a discounted rate of 15% off the AWP, as set forth in the ESI PBM Agreement for all years between 2012 and the present. In direct consultation with Express Scripts in the summer of 2007, Mallinckrodt set the inflated average wholesale price of Acthar used by Express Scripts for reimbursement. Since that time, Defendants have agreed to additional Acthar price increases, leading to the inflated prices paid by Plaintiff from 2011-2015.

85. As a result, ESI breached its agreements with IUOE Local 542 in at least two respects.

86. First, it conspired and agreed with Mallinckrodt to raise the AWP for Acthar in 2007, as set forth herein. It failed to contain the costs of Acthar, which directly and proximately caused the Acthar paid for by Plaintiff to be inflated. Worse, ESI agreed with Mallinckrodt to raise the AWP for Acthar in 2007, and each year up to the years in which IUOE Local 542 beneficiaries received the drug and Plaintiff paid for the drug, thereby causing further inflation in the AWP charged by ESI to IUOE Local 542.

87. Second, it failed to return the money paid by IUOE Local 542 in the form of “rebates”, as required by contract. For all years during the relevant time period, ESI agreed to pay IUOE Local 542 “100% of the rebates” it received from Mallinckrodt for Acthar. It failed to do so.

88. In the ESI PBM Agreement, “rebates” are defined as follows:

Rebates mean retrospective rebates that are paid to ESI pursuant to the terms of a rebate contract negotiated independently by ESI with a pharmaceutical manufacturer, and directly attributable to the utilization of certain Covered Drugs by Participants. Rebates do not include Manufacturer Administrative Fees; product discounts or fees related to the procurement of prescription drug inventories by or on behalf of ESI owned and operated specialty or mail order pharmacies; fees received by ESI from manufacturers for care management or other services provided

in connection with the dispensing of Specialty Products; or other fee-for-service arrangements whereby pharmaceutical manufacturers generally report the fees paid to ESI or its affiliates for services rendered as “bona fide service fees” pursuant to federal laws and regulations, including, but not limited to the Medicaid “Best Price” rule (collectively, “Other Pharma Revenue”). Such laws and regulations, as well as ESI’s contracts with pharmaceutical manufacturers, generally prohibit ESI from sharing any such “bona fide service fees” earned by ESI, whether wholly or in part, with any ESI client. ESI represents and warrants that it will not enter into any agreement with a pharmaceutical manufacturer for Other Pharma Revenue in exchange for a reduction of Rebates.

89. ESI did not pay to IUOE Local 542 all the “rebates ... directly attributable to the utilization of” the Acthar paid for by Plaintiff. It further entered into one or more agreements with Mallinckrodt for monies to paid to it that did not constitute “Other Pharma Revenue”, which had the effect of reducing the rebates that would have been otherwise payable to IUOE Local 542 in the absence of such agreements.

#### **ESI and Daraprim**

88. Turing Pharmaceuticals, LLC (“Turing”) acquired the rights to Daraprim and proceeded to increase the price 5000% from \$13.50 to \$750.00 per pill. One year’s course of treatment rose from \$6,500 to \$361,000.

89. Strikingly, ESI employed its market power to counter Turing’s action. It worked to create an alternative that was much less expensive than Daraprim.

90. On December 1, 2015, ESI announced that it would “partner with Imprimis Pharmaceuticals to drive access to a low-cost alternative to Daraprim.” *See*, “ESI Champions \$1 per Pill Access to an Alternative for Daraprim”, December 1, 2015, at: <http://lab.express-scripts.com/lab/insights/drug-options/express-scripts-champions-1-per-pill-access-to-an-alternative-for-daraprim>. In partnership with ESI, “Imprimis [] offer[ed] a compounded oral formulation of pyrimethamine and leucovorin (a form of folic acid) for as low as \$1 per capsule



for people whose pharmacy benefit is managed by ESI.” *Id.* When it is in ESI’s interest, it acts to “improve access and affordability.” *Id.*

91. ESI’s Chief Medical Officer, Dr. Steve Miller, stated that ESI found a way to deliver “a safe, high-quality and extremely cost-effective way to provide access to a Daraprim alternative.” However, because of its agreement with Mallinckrodt, ESI has *not* served as an effective agent for pharmaceutical buyers to seek to lower the cost of Acthar, or determine the availability of reasonably priced alternatives.

### **Acthar Pricing**

92. Mallinckrodt acquired the rights to Acthar from Aventis in 2001. At acquisition, the end payor price of a vial of Acthar was approximately \$40.00. After acquisition, Mallinckrodt raised the per vial, end payor price of Acthar to approximately \$748.00. From 2001 until Mallinckrodt executed its new strategy in 2007, the end payor price of Acthar grew to \$1,980.00.

93. When Mallinckrodt implemented its new strategy on August 27, 2007, the end payor price of Acthar rose to a staggering \$27,922.80 – that is, a 1,310% increase in the span of a month, and a 69,707% increase from the time Mallinckrodt acquired the drug. That was done in consultation with an agreement by Express Scripts, the new exclusive distributor.

94. Until Mallinckrodt obtained FDA approval for the IS indication, the price of Acthar remained relatively stable. However, on January 3, 2011, Mallinckrodt increased the price of Acthar 5%, another 5% on June 1, 2011, and executed a third price increase on December 27, 2011. In 2012, Acthar’s end payor price was \$34,150.00.

95. Near in time to Mallinckrodt plc’s \$5.9 billion acquisition of Questcor in 2014, the price of Acthar rose to \$40,840.80. this was after Questcor acquired the rights to Synacthen.

Under Mallinckrodt plc's stewardship, the end payor price of Acthar rose in 2016 to \$42,942.60, and to \$43,658.40 in 2017.

96. Since the acquisition of Acthar in 2001, the end payor price of Acthar has grown 109,046%, reflecting the precipitous rise in the value of the Acthar assets from \$100,000 in 2001 to \$5.9 billion in 2014 – a 5,899,900% increase in value. The dramatic increase in value of the Acthar assets, coupled with the durable and repeated ability to raise the price of Acthar, underscore the monopoly power wielded by Mallinckrodt in the ACTH market. Mallinckrodt's tactics described in this Complaint, however, reflect Mallinckrodt's willingness to undertake unfair and deceptive acts and practices in violation of Pennsylvania law.

**The Views of Express Scripts' Chief Medical Officer,  
Dr. Steve Miller, on Express Scripts' Market Power**

97. Beginning in 2007, Express Scripts became the exclusive agent of Mallinckrodt for the distribution of Acthar. *See* Freudenheim, *supra*. When Mallinckrodt chose to increase the price of this 50-plus year-old medication, Express Scripts did not push back. Instead, when confronted with the 2007 price increase, ESI's Chief Medical Officer Steve Miller stated that “[t]he increase was a manufacturing decision. I can’t comment on it.” *Id.*

98. The circumstances demonstrate why Dr. Miller chose to stay silent in the face of Express Scripts' decision to join Mallinckrodt in overcharging payors for Acthar in 2007.

99. By the time IUOE Local 542's beneficiaries were prescribed Acthar in 2011 through 2015, Express Scripts was handling each and every aspect of Acthar distribution through the above-described functions. CuraScript was the exclusive specialty pharmaceutical distributor, Accredo was the specialty pharmacy provider, and UBC coordinated both the product and money flows through the ASAP Program. As Mallinckrodt's exclusive agent, Express Scripts had no interest in lowering the price for Acthar because it was making money off all

aspects of its exclusive arrangement with the manufacturer. In other words, by helping Mallinckrodt maintain and enhance its monopoly power in the ACTH market, Express Scripts along with Mallinckrodt realized greater profits at the expense of payors like IUOE Local 542.

100. In the spring of 2017, ESI's Senior Vice President of Supply Chain and Specialty Pharma, Everett Neville, stated, "I don't think [Acthar is] a very great [drug] – it's a pretty poor drug with a very limited need and certainly [ESI's Chief Medical Officer, Dr.] Steve[Miller] could comment." Mr. Neville went on to say, "I think [Dr. Miller] and I both would agree, and **I think everybody in our company would agree, that [Acthar] is vastly overpriced for the value.**" (emphasis added). Mr. Neville stated that he "personally told [Mallinckrodt's] management team that their drug is hugely overpriced and that he "know[s] [Dr. Miller] has as well."

101. In the same public setting, Dr. Miller stated, "[i]f you look at the data, the indications for the drug are . . . in the compendium, it's listed under a lot of indications, its real use should be very, very limited. It's an old drug. There's better products in the marketplace and so we're going to continue to be very vigilant in our utilization management."

102. Despite this express acknowledgment by ESI's Chief Medical Officer, in the weeks and months following Mallinckrodt's settlement with the FTC, Express Scripts has not acted or made any efforts to contain costs or provide a reasonable alternative for Acthar.

103. Dr. Miller has articulated the power of Express Scripts in the prescription drug marketplace to extract lower prices for its customers, using its tremendous buying power and influence. He has made all of the following public comments:

"When I joined the company, we represented 12 million members. We're at 85 million today. That gives us extraordinary sway in the marketplace. If you think about any other aspect of health care, no one else has that

many lives that they can represent.”<sup>7</sup>

“We have tremendous scale, which allows us to get the best deals for our plan sponsors from both the pharmaceutical manufacturers and also the pharmacies. If any pharmacy chain ever becomes too large, we’re able to move our patients and ... get the lowest cost.”<sup>8</sup>

“I think that because of the continued escalation of cost, you need a PBM now more than ever. And what a best-in-class PBM like Express Scripts does really ensure is great health outcomes and more affordable costs.”<sup>9</sup>

“Pharma has shown that they feel very emboldened with their pricing power. We’re using our clout in the marketplace to really tamp these down for our clients.”<sup>10</sup>

“There are pharma companies that recognize this is in their best interest,” he says. “They, like us, want to get to a sustainable marketplace. They know if they’re overcharging for drugs that have very little efficacy, that puts them in a competitive disadvantage.”<sup>11</sup>

“Discussions to control costs have never been more important, as recent estimates put global drug spend at \$1.5 trillion by 2021, according to data

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<sup>7</sup> *Managed Care Magazine Online*, “A Conversation with Steve Miller, MD: Come in and Talk With Us, Pharma,” by Peter Wehrwein, April 2015, <https://www.managedcaremag.com/archives/2015/4/conversation-steve-miller-md-come-and-talk-us-pharma>

<sup>8</sup> *Business Insurance*, “Q&A: Dr. Steve Miller, Express Scripts Holding Co.,” by Shelby Livingston, May 22, 2016, <http://www.businessinsurance.com/article/00010101/STORY/305229991/Q&A-Dr-Steve-Miller,-Express-Scripts-Holding-Co>

<sup>9</sup> *Managed Care Magazine Online*, “A Conversation with Steve Miller, MD: Come in and Talk With Us, Pharma,” by Peter Wehrwein, April 2015, <https://www.managedcaremag.com/archives/2015/4/conversation-steve-miller-md-come-and-talk-us-pharma>

<sup>10</sup> *Nightly Business Report*, “Express Scripts Looks to Limit Drug Price Increases,” by Meg Tirrell, October 2, 2015, <http://nbr.com/2015/10/07/express-scripts-looks-to-limit-drug-price-increases/>

<sup>11</sup> *Medical Marketing and Media*, “Express Scripts’ Steve Miller Takes on Drug Industry in Pricing Battle,” by Jaimy Lee, February 1, 2015, <http://www.mmm-online.com/payersmanaged-markets/express-scripts-steve-miller-takes-on-drug-industry-in-pricing-battle/article/460559/>

from Quintiles IMS Holding. Yet sometimes, in the drug pricing debate, blame is placed on one part of the drug distribution system when, in fact, all of us – pharmaceutical companies, pharmacy benefit managers (PBMs), policymakers and payers – have a role to play in achieving better affordability and accessibility for medicine. As the largest PBM, our job is to make sure our patients, and our clients who provide them a pharmacy benefit, are getting medicines at the lowest net cost while working with our industry partners to make that possible.”<sup>12</sup>

“...[I]t is incumbent upon the pharmacy benefits managers to more forcefully illustrate the critical role we play in making medicine more affordable and accessible. For example, we partnered with a drug maker who was willing to lower the price of its hepatitis C drug. In doing so, we were able to provide 50,000 patients affordable access to this medication.”<sup>13</sup>

“The biggest problem is not new expensive drugs but repricing old ones, and not just ones being purchased by Martin Shkreli or Valeant. You have no new research. You have no innovation. You have nothing but increased drug prices.”<sup>14</sup>

“We are constantly trying to be vigilant and chase the bad actors out of the marketplace.”<sup>15</sup>

104. Through such statements, Express Scripts acknowledged its strong influence on pharmaceutical markets. The striking feature of the current circumstance is that Express Scripts has not asserted its influence to effectuate lower prices for Acthar.

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<sup>12</sup> *Real Clear Health*, “Is Drug Pricing at an Inflection Point?” by Dr. Steve Miller, April 14, 2017, [http://www.realclearhealth.com/articles/2017/04/14/is\\_drug\\_pricing\\_at\\_an\\_inflection\\_point\\_110550.html](http://www.realclearhealth.com/articles/2017/04/14/is_drug_pricing_at_an_inflection_point_110550.html)

<sup>13</sup> *Id.*

<sup>14</sup> *Forbes, Pharma & Healthcare*, “Solving Pharma’s Shkreli Problem,” by Matthew Herper, January 20, 2016, <https://www.forbes.com/sites/matthewherper/2016/01/20/solving-pharmas-shkreli-problem/#6dcce78c6be3>

<sup>15</sup> *The New York Times*, “Specialty Pharmacies Say Benefit Managers Are Squeezing Them Out,” by Katie Thomas, January 9, 2017, <https://www.nytimes.com/2017/01/09/business/specialty-pharmacies-say-benefit-managers-are-squeezing-them-out.html>

105. While acknowledging the “value” of the medication does not warrant its high prices, Express Scripts has facilitated, rather than forestalled, Mallinckrodt’s desire for ever growing profits by “repricing” an “old drug”.

106. With Acthar, “[y]ou have nothing but increased drug prices,” due in large part to Express Scripts’ decision to withhold its market power to effectuate cost containment through lower prices.

#### **The Mallinckrodt Synacthen Acquisition**

107. Since 2007, Acthar has represented 98% or more of Mallinckrodt’s revenue. Acthar was so important to Questcor that its then-CEO Don Bailey told investors it “is basically a single product company.”

108. Through its exorbitant Acthar price increases, Mallinckrodt was able to grow its revenue from Acthar sales from less than \$1 million in 2001 to \$798.9 million in 2013. Much of this increase occurred between 2011 and 2013 when Mallinckrodt’s revenues increased \$218.2 million to \$798.9 million. These are the years Plaintiff was paying for Acthar.

109. However, by 2013, Mallinckrodt identified a competitive threat. Novartis AG (“Novartis”) developed Synacthen Depot (cosyntropin depot) (“Synacthen”), a synthetically derived ACTH medication, which, like Acthar, could be injected intra-muscularly. While it was used outside the United States, it was not yet approved by the FDA for use in the United States. Recognizing that the entry of Synacthen in the United States market for ACTH drugs would threaten its exercise of its monopoly power, Mallinckrodt first attempted to buy the rights to Synacthen in 2009. It failed.

110. As of 2013, Novartis agreed to sell Synacthen to Retrophin, Inc., which at the time was helmed by Mr. Shkreli. Mr. Shkreli founded Turing (the maker of Daraprim) after he

departed Retrophin.

111. When faced with a competitive threat to its monopoly, Mallinckrodt disrupted the bidding process for Synacthen by intervening at the last minute to pay multiple times what had been offered by three competitors, including Retrophin. Retrophin had agreed to buy Synacthen for \$16 million. Upon learning of this imminent threat, Mallinckrodt acted to protect and enhance its monopoly power by licensing Synacthen for a minimum of \$135 million from Novartis. It licensed the United States exclusive rights to Synacthen from Novartis, not to bring this viable synthetic alternative to Acthar to market, but to eliminate the nascent competitive threat posed by an independently owned Synacthen. Mallinckrodt concealed its purpose for Synacthen, and has misrepresented its plans for Synacthen since it acquired the rights. Express Scripts has assisted Mallinckrodt in deceiving the public and payors like Plaintiff, about Mallinckrodt's true purpose for acquiring Synacthen, its true plans for Synacthen, and the impact Mallinckrodt's acquisition has had on Acthar pricing—maintaining inflated prices at the expense of payors.

112. These actions allowed Mallinckrodt and Express Scripts to aid one another in maintaining and enhancing Mallinckrodt's monopoly power in the ACTH market. The Synacthen acquisition had the purpose and effect of suppressing competition, and allowing Mallinckrodt to continue to raise prices for Acthar, which it did, unchecked by Express Scripts.

113. From 2013 through 2017, Mallinckrodt raised the price of Acthar from \$36,144 to \$43,658. Express Scripts did nothing to prevent these increases, or reduce costs for Acthar payors.

#### **The FTC Complaint Against Mallinckrodt**

114. On January 18, 2017, the Federal Trade Commission ("FTC") sued Mallinckrodt,



alleging that Mallinckrodt exercised, and continues to exercise, monopoly power in the United States in the sale of Acthar. *See generally*, Complaint for Injunctive Relief and Other Equitable Relief (“FTC Complaint”) at Exhibit “C” hereto.

115. The FTC alleged that such purchases “extinguished a nascent competitive threat to [Mallinckrodt’s] monopoly.” FTC Complaint, ¶ 1.

116. At all relevant times material to this case, Mallinckrodt possessed monopoly power – the ability to profitably raise price significantly above competitive levels without losing significant sales – in the relevant product market. None of the vast price increases taken by Mallinckrodt between 2007 and the present have caused a significant loss of sales. To the contrary, Mallinckrodt’s sales have increased during that time.

117. Mallinckrodt has repeatedly and profitably raised Acthar’s price from the time it acquired the product for \$100,000 in 2001 from Aventis to the present. Mallinckrodt has been able to raise prices unchecked, as set forth above, and achieve corresponding revenue growth to more than \$1 billion.

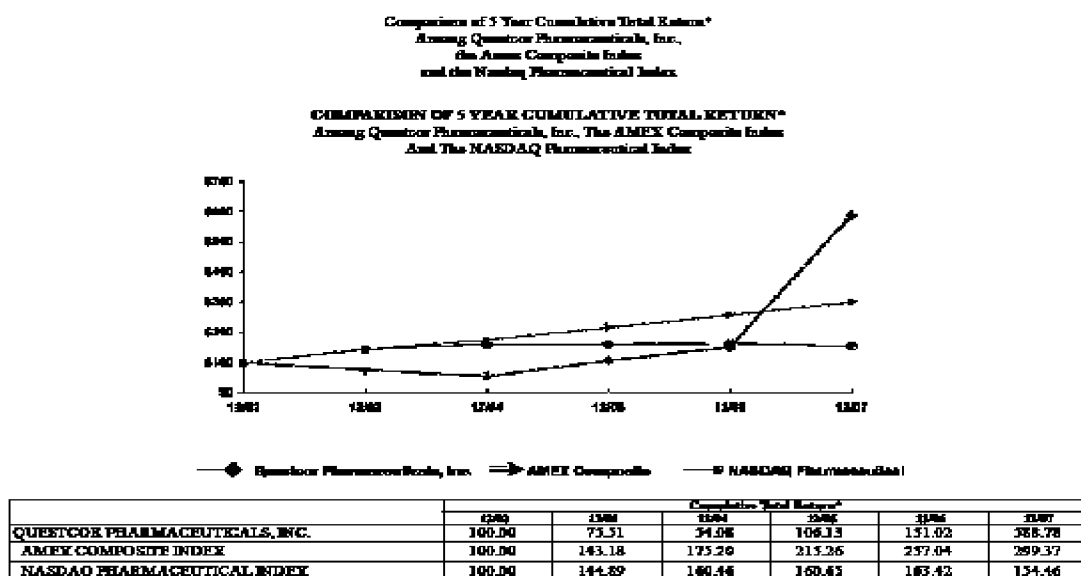
118. Mallinckrodt has encountered no competitive constraints on its ability to repeatedly increase Acthar’s price and, by extension, its revenue and profit margins. Mallinckrodt does not set the price of Acthar in reference to the price of any of the other drugs that are prescribed to treat the same indications that Acthar treats. Acthar is priced significantly higher than non-ACTH drugs used to treat the same indications, except for IS.

119. Indeed, one Mallinckrodt executive commented that the price for Acthar “was chosen by looking at the prices of other specialty drugs and estimating how much insurers and employers would be willing to bear.” Mallinckrodt took “some comfort that the strategy would work, and physicians would continue to use the drug, and payers would continue to pay.” In



fact, according to Mallinckrodt, “reality was better than expected.”

120. In its Annual Report on Form 10-K for the Fiscal Year ended December 31, 2007, Questcor illustrated the effect of its monopolization strategy on its “5 Year Cumulative Total Return”, illustrating a 290% return between 2006 and 2007 as follows:



\* \$100 invested on 12/31/02 in stock or index including reinvestment of dividends. Fiscal year ended December 31.

This stock performance graph shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

121. FDA approval is required to market pharmaceuticals to United States consumers. As a result, drugs sold outside of the United States are not viable competitive alternatives for United States consumers, even in the event of a significant price increase for ACTH drugs available in the United States.

122. Acthar has a 100% share of the market for ACTH drugs in the United States. No other ACTH drug is FDA-approved for therapeutic use.

123. The United States ACTH market is characterized by high barriers to entry. Developing a long-acting, depot-injection formulation of a drug product containing ACTH (natural or synthetic) that is stable, safe, and effective would require significant time, cost, and effort, with no guarantee of success. The requirements for entry include sourcing the active

pharmaceutical ingredient, formulating a sustained-release depot-injection formulation, scaling production to clinical scale, and successfully conducting clinical trials necessary for FDA approval. Mallinckrodt's former CEO, Don Bailey, assured investors that Acthar "has significant durability in the marketplace" because "it will be very difficult for this product to be replicated in any way [by] a generic."

124. Don Bailey also claimed that one of the barriers to entry in the marketplace is the Acthar drug formulation. While Acthar is a biologic extraction of porcine pituitaries, Bailey claimed, "[i]t's an undisclosed composition, so that's a trade secret." He also claimed "[t]he manufacturing process is also a trade secret. It's complex, it's unique, and we own all elements of the manufacturing process...The composition of Acthar that comes out of the manufacturing process is tied to the process, so if you don't know the process you can't figure out what's actually in Acthar."

125. If what the former CEO was saying was that Questcor enjoyed a natural monopoly, that does not necessarily imply the absence of market constraints. These constraints can come from a new competitive product or from a dominant buyer on the other side of the market. Both of these factors are relevant here.

**Mallinckrodt Engaged in Unfair and Deceptive Conduct  
By Acquiring the Only Competitor Drug, Synacthen**

126. Synacthen posed a threat to Mallinckrodt's ACTH drug monopoly, so Questcor intervened at the time when other firms were attempting to acquire the United States rights to Synacthen from Novartis. Questcor submitted a bid that included substantially more guaranteed money than the other bidders had offered, effectively ending the bidding process. By acquiring Synacthen, Questcor eliminated the possibility that another firm would develop it and compete against Acthar.

127. Synacthen constituted a nascent competitive threat to Questcor's ACTH drug monopoly. For years, Questcor viewed Synacthen as a significant potential competitive threat to its monopoly.

128. Nevertheless, in 2007, it adopted and pursued the above-described "new strategy", consolidating Acthar distribution to just one distributor and streamlining its control over sales and distribution through the implementation of ASAP. These functions were consolidated in one significant company, Express Scripts.

129. In 2009, Questcor approached Novartis about acquiring Synacthen. At that time, Questcor continued to view Synacthen as a possible future competitor, especially given the increasing prices Questcor was commanding for Acthar. Unsuccessful in that initial attempt, Questcor continued to monitor the competitive threat from Synacthen.

130. Then in 2012, Questcor again concluded that Synacthen posed a more immediate threat to Acthar if Synacthen was approved for sale in the United States.

131. By 2013, Questcor feared that if another company were to acquire Synacthen and obtain FDA approval, it could undermine its business model.

132. On information and belief, as long as Questcor believed no other firm was seeking to bring Synacthen to the United States, Questcor did not make further attempts to acquire it. Indeed, just months before Questcor began pursuing the acquisition of Synacthen, top Questcor officials questioned whether Synacthen would provide any affirmative value to Questcor.

**Other Bidders Planned to Use Synacthen to Challenge Acthar's Monopoly**

133. Unbeknownst to Questcor at the time, Novartis decided in late 2011 to divest exclusive rights to seek FDA approval for Synacthen and commercialize it in the United States, along with the marketing rights for Synacthen in over thirty-five other countries where the drug

was already approved and sold. Dozens of companies contacted Novartis and expressed interest in acquiring Synacthen. Three firms proceeded through several rounds of negotiations with Novartis, submitted formal offers, and drafted near-final agreements.

134. It is alleged that each of the three firms planned to develop Synacthen for IS and to use Synacthen to compete directly with Acthar. With this indication, each firm expected to capture a significant share of the United States ACTH market from Questcor by pricing Synacthen below Acthar's prices. Having the requisite pharmaceutical expertise and financing, the three firms independently conducted due diligence, crafted business plans and regulatory approval strategies, and took other affirmative steps in furtherance of developing Synacthen for the United States ACTH market.

#### **The Value of the Synacthen Assets**

135. The Synacthen assets and related rights provide a proven formulation for a long-acting, depot-injection drug containing synthetic ACTH. The drug product manufactured using the Synacthen formulation had been safely and effectively used to treat patients suffering from IS and other conditions worldwide for decades. The Synacthen assets would therefore facilitate commercializing a synthetic ACTH therapy in the United States.

136. The asset package being sold by Novartis included valuable trade secrets, including technical documentation detailing both the precise formulation for the Synacthen drug product and the manufacturing process.

137. In possession of the Synacthen assets, a buyer would not need to create a synthetic ACTH drug formulation *de novo*, nor would it need to develop from scratch the manufacturing and testing protocols necessary for production of the drug product.

**Questcor Disrupted the Synacthen Bidding Process**

138. It is alleged that on October of 2012, Questcor learned that at least one unidentified firm was attempting to acquire Synacthen from Novartis to develop it to compete with Questcor for the United States ACTH market. Questcor immediately reached out to Novartis, signed a confidentiality agreement with Novartis, and submitted a confidential offer for the purchase of Synacthen.

139. Novartis negotiated with the three alternative bidders in parallel with Questcor. By the spring of 2013, all three of the alternative bidders had submitted offers for Synacthen, with plans to develop and launch Synacthen in the United States in direct competition with Acthar. At the point where those negotiations left off, each company exchanged deal terms with Novartis and submitted formal offers. The offers by the three alternative bidders were comparable in value and structured similarly, and included an upfront payment, milestone payments upon FDA approval, and significant royalties on United States sales of Synacthen.

140. Unlike the three alternative bidders, Questcor had only incomplete plans for Synacthen and conducted limited due diligence when it submitted its initial offer to Novartis. Retrophin ultimately prevailed in the bidding war with a bid of \$16 million.

141. However, on June 11, 2013, the day Retrophin was to sign its agreement with Novartis, Questcor and Novartis entered into a Licensing Agreement, Asset Purchase Agreement, and Supply Agreement (collectively, “the Agreements”). By the Agreements, Questcor gained the exclusive rights to develop, market, and sell Synacthen in the United States and over thirty-five other countries. Under the Agreements, Questcor was obligated to pay a minimum of \$135 million, and likely \$300 million, to Novartis for Synacthen.

142. In other words, Questcor swept in at the eleventh hour to overpay—at least 8

times more than the market had determined—for the only immediate competitive threat to its monopoly for Acthar. Despite paying this amount, they did not seek FDA approval to bring the product to market.

**The Lawsuit Between Retrophin and Questcor for Questcor’s Antitrust Violations**

143. In January 2014, Retrophin sued Questcor for antitrust violations in the United States Federal District Court for the Central District of California. *See, Retrophin, Inc., v. Questcor Pharmaceuticals, Inc.*, CV-14-00026-JLS (C.D.Cal) (“*Retrophin Complaint*”) at Exhibit “D” hereto. To the extent relevant to Plaintiff’s Complaint, the averments regarding antitrust conduct interposed by Retrophin are incorporated by reference herein.

144. In the *Retrophin Complaint*, Retrophin claimed:

In June of 2013, plaintiff Retrophin was poised to challenge Questcor’s monopoly. It had negotiated an agreement to purchase from Novartis AG (“Novartis”), the rights to sell in the US a product called Synacthen. ...

Retrophin planned to obtain FDA approval to sell Synacthen in the US and compete head to head against Questcor by dramatically undercutting Questcor’s price for Acthar. It had negotiated and was ready to sign an agreement to purchase the US rights to Synacthen from Novartis. The signing was scheduled for June 11, 2013. The signing of the agreement was so imminent that a press release had been prepared to announce the deal.

On June 11, 2013, the day Retrophin was to sign its agreement with Novartis, Questcor swept in and acquired the rights to Synacthen. In doing so, it preserved and entrenched its ACTH monopoly in the US and eliminated the competitive threat posed by Retrophin’s acquisition of Synacthen. There was no procompetitive aspect of Questcor’s acquisition of Synacthen.

*Retrophin Complaint*, ¶¶ 4-6, at Exhibit “D”.

145. The FTC apparently agreed with Retrophin’s assessment.

146. The government, in its 2017 FTC complaint, mirrored Retrophin’s 2014 allegations that Questcor engaged in anticompetitive conduct in violation of antitrust laws.

147. Mallinckrodt chose to settle the lawsuit with Retrophin for \$15.5 million, slightly less than the \$16 million Retrophin bid to purchase Synacthen from Novartis.

**Mallinckrodt's Acquisition of Synacthen Harmed Consumers, like Plaintiff**

148. Mallinckrodt's strategy to protect its monopoly power in the market for ACTH drugs was successful. But-for Mallinckrodt's acquisition of Synacthen, one of the three alternative bidders, including Retrophin, would have acquired Synacthen and pursued its plan to develop Synacthen for IS to compete directly with Acthar at a lower price. With the acquisition of Synacthen, and the agreement of Express Scripts to not object, Mallinckrodt was able to thwart an imminent threat to its Acthar monopoly and thereby harmed competition.

149. Mallinckrodt misrepresented why it acquired Synacthen: it claimed that it acquired Synacthen to develop it for new, non-Acthar indications, but given the similarities between the two drugs, any therapeutic indication that Mallinckrodt was to pursue for Synacthen could easily have been pursued for Acthar. Mallinckrodt never brought Synacthen to market.

150. Fourteen months after acquiring Synacthen, Mallinckrodt acquired Questcor for \$5.9 billion. The vast majority of Questcor's value was attributable to Acthar and Synacthen.

151. However, despite its claims, Mallinckrodt has not brought Synacthen to market for any indication. Instead, it keeps Synacthen off the market to protect its monopoly power and high prices for Acthar. It took the FTC to force Mallinckrodt to release Synacthen from its hold. Express Scripts did nothing.

**Mallinckrodt settles with the FTC**

152. On January 18, 2017, the FTC announced that Questcor and its parent Mallinckrodt agreed to pay \$100 million to settle FTC charges that Questcor and Mallinckrodt violated antitrust laws when Questcor acquired the rights to Synacthen from Novartis in 2013.

153. According to FTC Chairwoman Edith Ramirez, “Questcor took advantage of its monopoly to repeatedly raise the prices of Acthar, from \$40 in 2001 (when it acquired the rights to sell Acthar for \$100,000) to more than \$34,000 per vial today – an 85,000 percent increase.”

154. The brunt of these monopoly prices was borne by self-funded payors, like IUOE Local 542, located throughout the country, whose beneficiaries and patient members [had children] or [were afflicted] with [IS] or [MS] and were at the mercy of Mallinckrodt.

155. From the time it sought FDA approval for the treatment of IS, Mallinckrodt has raised the price of Acthar to over \$43,000.

156. Questcor claimed that these exorbitant price increases were in response to demand. But its former Chief Executive Officer, Don Bailey, acknowledged in 2009 that “we only have about 800 patients a year. It’s a very, very small – tiny – market.” Consequently, the limited use of the product did not justify an over 58,000% price increase from acquisition until 2009.

157. Since the Acthar market for the treatment of IS was so limited, Questcor sought to expand its use. By 2012, Acthar was prescribed for Medicare recipients 3,387 times. To Medicare alone, this represented a cost of \$141,500,000 in 2012.

158. Quantified another way, Dr. William Shaffer, a neurologist in Greeley, Colorado who was the highest prescriber of Acthar in 2012, wrote only 78 prescriptions for the drug, but the prescribed Acthar cost Medicare \$4,000,000.

159. Acthar represented 98% or more of Questcor’s sales and revenue from sales since 2007. Its manipulation of the market has resulted in a 266% increase in revenue year-over-year from 2011 to 2013. Total net sales for Questcor in 2011 were \$218.2 million, \$509.3 million in 2012, and \$798.9 million in 2013. In each of those years, Acthar represented at least 95% of



Questcor's net sales – over \$1.45 billion in revenue.

160. In the words of then-CEO Don Bailey, “Questcor is basically a single-product company.” But, by flexing its monopoly power, Questcor has been able to raise Acthar prices and increase revenue from Acthar in a “tiny market” from less than \$1 million for fiscal year 2001 to \$799 million for fiscal year 2013 – a nearly 80,000% increase. It did so in conjunction with Express Scripts.

161. Mallinckrodt's decision to exclusively contract with the agent for its largest customer to provide limited distribution for Acthar removed ESI's competitive pressure in the marketplace to cause Acthar prices to be lower. Instead, by entering into an exclusive arrangement with Express Scripts, Mallinckrodt was able to enhance its monopoly power and to raise its Acthar prices above competitive prices throughout the relevant time period from 2007 through the present.

162. The FTC forced Mallinckrodt to divest itself of the marketing rights to Synacthen in the United States. In conjunction with the announced settlement, on January 18, 2017 Mallinckrodt issued a press release explaining that, “[u]nder the agreement, Mallinckrodt will license [Synacthen] to a licensee identified by the FTC as Marathon Pharmaceuticals, LLC, to develop and pursue possible U.S. [FDA] approval of Synacthen Depot in two indications – Infantile Spasms (IS) and Nephrotic Syndrome (NS).”

163. Importantly, Mallinckrodt admitted the following about the market for ACTH products:

Synthetic ACTH products are relatively common – Synacthen Depot and others have been on the market outside of the U.S. for years, if not decades – and in Mallinckrodt's view are not especially complex to either formulate or manufacture at scale. However, history has borne out the FTC's view that there are “high barriers to entry” for a synthetic ACTH in the U.S. market. Synacthen Depot has never been FDA-approved for use

in the U.S. In fact, in all the time it has been commercially available, no owner (including the owner prior to Questcor) ever undertook U.S. development in any indication until after the Questcor acquisition when Mallinckrodt began preparation for development in DMD (Duchenne Muscular Dystrophy).

164. In July, 2017, The FTC announced that it had approved a sublicense submitted by Mallinckrodt “granting West Therapeutic Development, LLC certain rights to develop and market” Synacthen. The FTC explained, “[u]nder the January [settlement] order, the FTC approved Marathon Pharmaceuticals, LLC as the sublicensee. Marathon has since spun off the assets and personnel related to the development of a synthetic ACTH drug to West Therapeutic Development, LLC.”

165. In its own press release, Mallinckrodt noted that it retained the rights to “continue to develop the product for all *other* indications in the U.S.”, beyond IS and NS (emphasis in original). “Mallinckrodt is doing so under the development name MNK-1411 and has filed an Investigational New Drug (IND) application with the FDA to assess the drug’s potential in the treatment” of other diseases. “The company completed a phase 1 study for MNK-1411...”, and expected a “phase 2 trial” later in 2017. Mallinckrodt pointed out that the “FDA has granted Mallinckrodt’s request for a Fast Track designation for its IND application”, demonstrating that both Questcor and Mallinckrodt could have done so long before 2017.

**COUNT I**  
**INTERNATIONAL UNION OF OPERATING ENGINEERS LOCAL 542**  
**v.**  
**ALL DEFENDANTS**  
**Pennsylvania Unfair Trade Practices and Consumer Protection Law**

166. Plaintiff hereby incorporates by reference the preceding and following averments as if fully set forth herein and further alleges as follows.

167. Pennsylvania’s Unfair Trade Practices and Consumer Protection Law, 73 Pa. Stat.

Ann. §§201, et seq. (“UTPCPL”) makes unlawful any “unfair methods of competition” and “unfair or deceptive acts or practices”, including the following, among others:

- (ii) Causing likelihood of confusion or of misunderstanding as to the source, sponsorship, approval or certification of goods or services;
- (v) Representing that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits or quantities that they do not have or that a person has a sponsorship, approval, status, affiliation or connection that he does not have;
- (vii) Representing that goods or services are of a particular standard, quality or grade, or that goods are of a particular style or model, if they are of another;
- (viii) Disparaging the goods, services or business of another by false or misleading representation of fact;
- (xi) Making false or misleading statements of fact concerning the reasons for, existence of, or amounts of price reductions; and
- (xxi) Engaging in any other fraudulent or deceptive conduct which creates a likelihood of confusion or of misunderstanding.

168. The unfair methods of competition, and unfair or deceptive acts or practices, in the conduct of any trade or commerce as defined above are declared unlawful under the UTPCPL.

169. Defendants engaged in the following unfair and deceptive acts or practices, which violate the aforesaid provisions of the UTPCPL:

- a. By entering into the exclusive distribution arrangement described herein in 2007, and not disclosing the same to IUOE Local 542, Defendants engaged in deceptive acts and made misrepresentations to Plaintiff that impeded Plaintiff’s efforts to contain costs for specialty drugs like Acthar, and then sending bills for Acthar which charged the artificially inflated prices which Defendants agreed amongst themselves to charge Plaintiff. This caused at least a likelihood of confusion or of misunderstanding as to the source, sponsorship, approval and/or certification of Acthar sold by Mallinckrodt, misrepresented the same, and/or constituted fraudulent or deceptive conduct which created a likelihood of confusion or a misunderstanding by Plaintiff.

- b. Defendants conspired and agreed to adopt the above-described ASAP program and the ASAP form (Exhibit “A” hereto) in 2007, and to maintain the Program and form through 2011-2015 (when Plaintiff paid for Acthar), in order to mislead and deceive IUOE Local 542 and its beneficiaries about Express Scripts’ direct role as the “hub” of patient care as it concerns the medical conditions for which Acthar is indicated, and to bypass Plaintiff’s efforts to contain and reduce costs for specialty drugs.
- c. Starting in July 2007, Mallinckrodt issued a misleading and deceptive announcement about its new distribution strategy, but the announcement failed to disclose that more than pharmacy distribution was being handed over to Express Scripts; all aspects of distribution, pricing and product sales were now being handled by Express Scripts, and its wholly-owned subsidiaries, as part of a “hub” of services for which Mallinckrodt contracted.
- d. Express Scripts made material misrepresentations and engaged in deception about its contractual relationships with Mallinckrodt and the real reasons for the exorbitant Acthar price increases between August 2007 and 2015. In 2007, when asked directly about the huge price increase, Dr. Miller of Express Scripts’ misled and deceived the public by claiming “[t]he increase was a manufacturing decision. I can’t comment on it.” In truth, it was a joint decision by Defendants, reflected in contracts between them.
- e. Express Script’s Dr. Miller and Express Scripts remained silent about the truth about Acthar’s “value” for years, so that Express Scripts could continue to charge false, misleading and excessive prices for Acthar to payors like Plaintiff. In fact, it was not until the spring of 2017 – 6 years after Plaintiff made its first payment for Acthar—that Express Scripts admitted Acthar was not worth the price Express Scripts and Mallinckrodt were charging for it. That year, ESI’s Senior Vice President of Supply Chain and Specialty Pharma, Everett Neville, stated, “I don’t think [Acthar is] a very great [drug] – it’s a pretty poor drug with a very limited need and certainly [ESI’s Chief Medical Officer, Dr.] Steve[Miller] could comment.” Mr. Neville went on to say, “I think [Dr. Miller] and I both would agree, and I think everybody in our company would agree, that [Acthar] is vastly overpriced for the value.” Mr. Neville stated that he “personally told [Mallinckrodt’s] management team that their drug is hugely overpriced and that he ‘know[s] [Dr. Miller] has as well.’” In the same public setting, Dr. Miller stated, “[i]f you look at the data, the indications for the drug are . . . in the compendium, it’s listed under a lot of indications, its real use should be very, very limited. It’s an old drug. There’s better products in the marketplace and so we’re going to continue to be very vigilant in our utilization management.” These revelations came

far too late to save Plaintiff from being overcharged for Acthar, and demonstrate that Defendants conspired and agreed to commit acts or practices in violation all of the above-described sub-sections of 73 Pa. Stat. Ann. §§201. For instance, Express Scripts misled Plaintiff and deceived Plaintiff about its approval of Acthar and the benefits of Acthar as a valuable specialty drug “worth” what it and Mallinckrodt were charging, in relation to other drugs and treatments (in violation of subsections (ii), (v), (vii), (viii)).

- f. Defendants misled and deceived IUOE Local 542 and the public about their direct relationship, their joint decision to raise the prices of Acthar, and the lack of value of Acthar for the prices being charged, in order to intentionally and deceptively charge false, misleading and excessive prices for Acthar, during the period between 2007 (when they entered into their exclusive distribution arrangement), through 2013 (when Mallinckrodt acquired Synacthen in 2013 and Express Scripts did nothing about it), and up to at least 2017 when Express Scripts began to tell the truth. Express Scripts then offered discounts off the inflated prices of Acthar which were far less than the discounts offered for either brands or generics, while failing to disclose the truth about the pricing disparity for Acthar (even with the discounts), thereby misleading Plaintiff as to the reasons for, existence of, or amounts of the Acthar price reductions, in violation of sub-section (xi).
- g. Defendants acts or practices, including the failures to act and to speak the truth in the face of false, misleading and deceptive statements about Acthar’s pricing, distribution and value, constitute “other fraudulent or deceptive conduct which creates a likelihood of confusion or of misunderstanding, in violation of sub-section (xxi).

170. The UTPCPL authorizes any person, including natural persons, corporations, trusts, partnerships, incorporated and unincorporated associations, and any other legal entities to seek an injunction, damages, costs, and reasonable attorneys fees to prevent and ameliorate the anticompetitive conducted described herein.

171. IUOE Local 542 is a person pursuant to the UTPCPL. IUOE Local 542 has been injured as a result of the Defendants’ conduct in violation of Pennsylvania law, and hereby seeks damages. Plaintiff has purchased or reimbursed the costs of multiple administrations of Acthar distributed by Defendants directly to IUOE Local 542’s beneficiaries for their personal, family or

household use and purpose. Because IUOE Local 542 beneficiaries paid only minimal co-pays (between \$20 to \$40), IUOE Local 542 paid the bulk of the inflated prices of Acthar directly to Express Scripts, and, in turn, to Mallinckrodt.

172. The acts and practices described herein demonstrate that Mallinckrodt and Express Scripts acted unlawfully within the meaning of the UTPCPL such that IUOE Local 542 may be awarded up to three times its actual damages sustained, and such additional relief as deemed necessary or proper. These damages consist of, *inter alia*, the difference between the true price of Acthar before Mallinckrodt engaged with Express Scripts beginning in 2007 to artificially inflate the “average wholesale price” of Acthar, as required by contract to be charged, and the inflated prices of Acthar charged to Plaintiff in 2014 and 2015.

173. IUOE Local 542 seeks relief against Mallinckrodt and Express Scripts for their unfair and deceptive conduct which allowed Defendants to raise and fix the prices of Acthar at supra-competitive levels, and to maintain Mallinckrodt’s monopoly power in the market for ACTH drugs allowing unfettered price increases.

174. Mallinckrodt and Express Scripts agreed to raise the prices of Acthar.

175. IUOE Local 542 was injured as a direct result of the Defendants’ conduct in violation of the UTPCPL sections above, and hereby seeks damages.

**WHEREFORE**, International Union of Operating Engineers Local 542 demands that judgment be entered in its favor and against Defendants in an amount to be determined at trial, including but not limited to costs, attorneys’ fees, and such other relief deemed just and appropriate by this Court.

**COUNT II**  
**INTERNATIONAL UNION OF OPERATING ENGINEERS LOCAL 542**  
**v.**  
**ALL DEFENDANTS**  
**Negligent Misrepresentation**

176. Plaintiff hereby incorporates by reference the preceding and following averments as if fully set forth herein and further alleges as follows.

177. Defendants' acts violate Pennsylvania common law against negligent misrepresentation.

178. Negligent misrepresentation requires proof of (1) a misrepresentation of a material fact; (2) made under circumstances in which the misrepresenter ought to have known of its falsity; (3) with an intent to induce another to act on it; and (4) which results in injury to a party acting in justifiable reliance on the misrepresentation.

179. Defendants made misrepresentations of material fact, as detailed herein. For instance, in setting the AWP-based prices for Acthar, which prices IUOE Local 542 paid, the Defendants made material misrepresentations that those prices represented a calculation of real and fact-based prices for their drugs, and that they represented the actual value of the product in the marketplace. Defendants called these prices "average wholesale prices" and when they knew they were not. They did so intending to induce Plaintiff to pay such "average wholesale prices" for Acthar, and IUOE Local 542 in fact, justifiably relied upon such prices in paying them.

180. As set forth herein, Mallinckrodt made multiple misrepresentations about the value of Acthar, in relation to their high prices set by Defendants. Mallinckrodt knew that these representations were false yet they made them intending to induce payors like Plaintiff to pay for Acthar. Plaintiff, in fact, justifiably relied on statements of value, as reflected in Express Scripts placing Acthar on a list of "specialty" drugs, for which deep discounts on brands and generics



were unavailable.

181. As set forth above, Express Scripts made material misrepresentations about the reason for the Acthar price increases, which it knew at the time were due to its exclusive arrangements with Mallinckrodt, not “a manufacturing decision”. These misrepresentations were advanced by the ASAP Program and forms, which were made to appear as if some third-party was conducting the program, rather than Express Scripts and its wholly owned subsidiaries. In including Acthar among its list of “specialty drugs”, and carving it out from the discounts Plaintiff negotiated for branded and generic drugs under its contract, Express Scripts intentionally or negligently placed Acthar under a “special” list so that Plaintiff would be deceived by relying upon such classification, and higher pricing.

182. These representations were material to the transactions at hand in that IUOE Local 542 used and relied upon these inflated prices as the basis for the amount to pay and/or reimburse for Acthar under the specialty drug provisions of its contract.

183. Defendants knew or should have known of the falsity of their misrepresentations, especially as to the purported value of Acthar. Mallinckrodt bought the drugs for \$100,000 when it cost only \$40. And Express Scripts in the business of understanding the value of drugs in order to make recommendations to its clients, like Plaintiff. Thus, Defendants, having spoken about the purported value of Acthar in relation to is high pricing had a duty to speak the truth.

184. As set forth more fully above, the prices communicated by Defendants to payors like Plaintiff were artificial prices, unrelated to any actual, reasonable price in the marketplace, or actual value of Acthar. Instead, they were intentionally created and manipulated by the Defendants for the purpose of generating exorbitant revenue, thus constituting false representations which the Defendants knew or, in the absence of recklessness, should have



known to be false.

185. The Defendants made these false representations about the actual prices for and value of Acthar with the intent of misleading IUOE Local 542 into relying on the prices as real and fact-based prices, rather than artificially inflated prices.

186. IUOE Local 542 justifiably relied upon these false misrepresentations in purchasing and/or reimbursing Acthar at the amount charged by Express Scripts based on the prices set jointly by Mallinckrodt and Express Scripts. As a result, Plaintiff was injured by paying more for Acthar than it should have.

187. IUOE Local 542's contracts with Express Scripts provided for cost containment and for discounted prices for specialty drugs at varying rates, intended to reflect the efforts of Express Scripts to provide cost containment as a principal PBM service. It is Express Scripts' "business, profession, and employment" to know about the value of the drugs it contracts with manufacturers to supply and payors to pay for. The prices for Acthar set forth in such contracts were prices set by Mallinckrodt, along with Express Scripts, who agreed to use the AWP as jointly established at an inflated level in its contracts with payors, like Plaintiff. As such, all Defendants communicated these false prices directly to IUOE Local 542 for the Acthar sold.

188. The Pennsylvania Supreme Court has expressly adopted several aspects of the Restatement (Second) of Torts relevant to Plaintiff's claims. For instance, Section 542, which is titled "Information Negligently Supplied for the Guidance of Others", provides, in pertinent part: (1) one who, in the course of his business, profession, or employment, or in any other transaction in which he has a pecuniary interest, supplies false information for the guidance of others in their business transactions, is subject to liability for pecuniary loss caused to them by their justifiable reliance upon the information, if he fails to exercise reasonable care or competence in obtaining

or communicating the information. (2) ...[T]he liability stated in (1) is limited to loss suffered (a) by the person or one of a limited group of persons for whose benefit and guidance he intends to supply the information or knows that the recipient intends to supply it; and (b) through reliance upon it in a transaction that he intends the information to influence or knows that the recipient so intends or in a substantially similar transaction.”

189. Here, both sets of Defendants are “expert suppliers of information” about prescription drugs, which information is widely disseminated to the public in general, and medical community in particular, in order to induce justifiable reliance on the information being supplied. Mallinckrodt is the manufacturer of Acthar, and an expert to whom patients (like the Plaintiff-beneficiaries who took Acthar), payers (like Plaintiff), doctors (like the prescribers of the Acthar here), PBMs (like Express Script) and others look for information about value, pricing and safety of its drugs. So too, Express Scripts is in the business of knowing about drug value and pricing, and payers like Plaintiff justifiably rely on the information it supplies about specialty drugs, like Acthar.

190. Both sets of Defendants supplied information described herein “in the course of [their] business, profession, or employment”. Both supplied false and misleading information for the guidance of the IUOE Local 542 patients and the Plaintiff itself in course of business transactions involving the distribution, sales and payment for Acthar. Plaintiff justifiably relied on such information in paying the high prices for Acthar being charged over the course of 2 years. Both sets of Defendants failed to exercise reasonable care or competence in the promulgation of false information about the value of Acthar, as evidenced by Express Scripts’ 2017 revelations that Acthar was not worth what was being charged for it. Plaintiff is entitled to recover for its losses suffered, since IUOE Local 542 and its beneficiaries are persons for whose

benefit and guidance Defendants intended to supply the information of Acthar value and the Defendants knew or should have known IUOE Local 542 and its beneficiaries would receive such information.

191. As a direct and proximate result of the misrepresentations of the Defendants, as set forth above, IUOE Local 542 was harmed in that it justifiably relied on the negligent misrepresentations of Defendants about the value of Acthar in relation to its high prices. Plaintiff was unaware of the artificial, inflated prices of Acthar, and would not have paid and/or reimbursed the artificially inflated prices for Acthar had it known of the misrepresentations of material fact made by Defendants. Plaintiff overpaid for the Acthar because of the misrepresentations.

**WHEREFORE**, International Union of Operating Engineers Local 542 demands that judgment be entered in its favor and against Defendants, in an amount to be determined at trial, including but not limited to costs, attorneys' fees, and such other relief deemed just and appropriate by this Court.

**COUNT III**  
**INTERNATIONAL UNION OF OPERATING ENGINEERS LOCAL 542**  
**v.**  
**ALL DEFENDANTS**  
**Aiding and Abetting/Conspiracy**

192. Plaintiff hereby incorporates by reference the preceding and following averments as if fully set forth herein and further alleges as follows.

193. As set forth more fully above, beginning at least as early as 2007, the exact date being unknown to the Plaintiff, and continuing thereafter until the present, Defendants and other unnamed co-conspirators, between and among themselves and others, entered into an agreement and/or otherwise engaged in a continuing conspiracy to defraud and deceive the Plaintiff by

causing it to pay more for Acthar than it otherwise would have paid in the absence of the Defendants' conspiracy and concerted action.

194. Pursuant to the unfair and deceptive scheme to distribute, market and sell Acthar at high prices which bore no reasonable relation to the value of the drug Express Scripts ascribed to it in 2017, and the conspiracy alleged herein, and in furtherance thereof, Defendants and their co-conspirators engaged in a wide range of activities, the purpose and effect of which was to defraud, deceive and misinform IUOE Local 542 as to the truth about Acthar pricing and value, and acted or took substantial steps in furtherance of the conspiracy. Those acts include the following:

- a. discussing and agreeing among themselves and with their co-conspirators that they would directly control the price at which IUOE Local 542 paid for Acthar far above the reasonable value of the drug;
- b. discussing and agreeing among themselves and with their co-conspirators that they would increase the price at which IUOE Local 542 paid for Acthar;
- c. discussing and agreeing among themselves and with their co-conspirators that they would jointly implement and directly control the ASAP program, and associated materials and website, which enrolled patients into an exclusive distribution network for the administration of Acthar, allowing Defendants to raise the prices unchecked and to conduct their unfair pricing scheme for Acthar;
- d. discussing and agreeing among themselves and with their co-conspirators that they would directly control the exclusive distribution network for Acthar through CuraScript, and then Accredo, and the ASAP Program through UBC and its predecessors;
- e. discussing and agreeing among themselves and with their co-conspirators that they would rely on employees to promote the ASAP Program through the marketing alleged herein;
- f. discussing and agreeing among themselves and with their co-conspirators that they would conceal and suppress the truth about

the Acthar inflated prices, Acthar true value, the monies earned from payors like IUOE Local 542, and their exclusive arrangement to maintain and enhance Mallinckrodt's monopoly power and raise prices as alleged herein.

195. In addition to the specific facts set forth above, it is alleged the Defendants and their co-conspirators engaged in conspiratorial meetings, among the purposes of which meetings were to discuss the importance of controlling the direct distribution, marketing, sale and administration of Acthar to payors like IUOE Local 542, and deriving substantial profits from these activities. These meetings took place in the summer of 2007, when Defendants were negotiating the contracts that form their exclusive agreement. The meetings and communications continued thereafter when Mallinckrodt raised the prices for Acthar to its current exorbitant levels. They also took place in 2013 when Mallinckrodt purchased Synacthen, but decided to not bring the competitive produce to market. They also likely took place after Retrophin and the FTC sued, and Mallinckrodt settled for millions.

196. There was a common design pursuant to which Defendants carried out their tortious acts of negligently misrepresenting the truth about Acthar and their exclusive arrangements, and the acts or practices in violation of the UTPCPL. The common designed involved *inter alia*, misleading patients and payors, like Plaintiff, about the value of Acthar in relation to its high prices, and concealing the truth about Acthar and their exclusive arrangements.

197. There was a common design pursuant to which Defendants carried out their tortious acts of negligently misrepresenting the truth about Acthar and their exclusive arrangements, and the acts or practices in violation of the UTPCPL. The common design involved *inter alia*, misleading patients and payors, like Plaintiff, about the value of Acthar in relation to its high prices, and concealing the truth about Acthar and their exclusive

arrangements.

198. Here, Express Scripts aided and abetted Mallinckrodt's unlawful act, practices, misrepresentations, omissions and deception, knowing that Mallinckrodt was breaching its duty to tell the truth, having spoken publicly about Acthar. Mallinckrodt, in turn, aided and abetted Express Scripts in breaching its obligations to IUOE Local 542 by continuing to provide Express Scripts with a lucrative exclusive arrangement in exchange for concealing and suppressing the truth about Acthar's lack of value. Both Defendants gave substantial assistance to the other in accomplishing their tortious conduct, and their conduct in so assisting breach, a separate duty to the Plaintiff.

199. The Defendants performed the conspiratorial acts set forth herein intending to injure payors of Acthar, like IUOE Local 542, by causing them to pay inflated prices so that the Defendants could derive substantial profits.

200. The Defendants performed the acts alleged herein in furtherance of the common plan or design for the conspiracy with intent and/or with knowledge of the injury and damage it would cause to IUOE Local 542, and with knowledge and intent to cause such injuries and/or with reckless disregard for the consequences. These acts were either unlawful (as in the case of the acts described in Counts I and II) or lawful by an unlawful means as for an unlawful purpose (as in the case of Defendants' willful silence in the face of its co-defendants' misinformation and misrepresentations).

201. As a direct and proximate result of the Defendants' conspiracy and aiding and abetting as alleged herein, IUOE Local 542 has been injured and damaged, and the Defendants are jointly and severally liable for such injuries and damages.

**WHEREFORE**, International Union of Operating Engineers Local 542 demands that judgment be entered in its favor and against Defendants, in an amount to be determined at trial, including but not limited to costs, attorneys' fees, and such other relief deemed just and appropriate by this Court.

**COUNT IV**  
**INTERNATIONAL UNION OF OPERATING ENGINEERS LOCAL 542**  
**v.**  
**EXPRESS SCRIPTS AND MALLINCKRODT**  
**Unjust Enrichment**

202. Plaintiff hereby incorporates by reference the preceding and following averments as if fully set forth herein and further alleges as follows.

203. This Count alleges unjust enrichment against both Express Scripts and Mallinckrodt.

204. IUOE Local 542 agreed to retain Express Scripts' services exclusively and in good faith and in reasonable reliance on Express Scripts' conduct and representations described herein.

205. Among other things, IUOE Local 542 at all times had a reasonable expectation that Express Scripts' conduct would result in affordable services, including cost containment and reasonable pricing for the value of specialty drugs, like Acthar.

206. IUOE Local 542 and its beneficiaries made direct payments to Express Scripts which were valuable to Express Scripts, and Express Scripts was unjustly enriched by such direct payments, in that, the reimbursement rates charged by Express Scripts at extremely high prices with inequitable discounts were valuable and beneficial to Express Scripts.

207. It is believed and therefore averred that these payments made to Express Scripts were then used to compensate Mallinckrodt for the dosages of Acthar supplied to IUOE Local

542 beneficiaries. Plaintiff is aware of direct contractual relations between Defendants which will demonstrate these money flows which directly benefitted both Defendants. Discovery in this case will prove the truth of these averments.

208. By engaging in the conduct described herein, Express Scripts and Mallinckrodt have knowingly obtained benefits from IUOE Local 542, namely grossly inflated revenue from Express Scripts' direct involvement in coordinating all aspects of IUOE Local 542's receipt of and payments for Acthar, under circumstances such that it would be inequitable and unjust for either Express Scripts or Mallinckrodt to retain such benefits.

209. By engaging in the unlawful conduct described herein, Express Scripts and Mallinckrodt have been knowingly enriched by the amount charged for Acthar over and above what they could have charged in a competitive market, wherein Express Scripts would have used its market power to extract lower prices from Mallinckrodt in fulfillment of its obligation to contain costs and provide drug pricing value, and what it could have charged if it had engaged in appropriate cost containment measures.

210. By assisting Mallinckrodt in maintaining and enhancing its monopoly, and its exercise of monopoly power through increasing prices over a decade, and engaging in other unlawful acts and practices described herein, Express Scripts was able to extract exorbitant revenue from IUOE Local 542 for its benefit and the benefit of its principal Mallinckrodt beyond what the Defendants could have received in the absence of such unlawful conduct. This conduct violated state consumer fraud laws, as well as the common law of Pennsylvania, and as such, interfered with the legally protected interests of IUOE Local 542.

211. IUOE Local 542 is therefore entitled to an award of compensatory damages in an amount to be determined at trial, or the imposition of a constructive trust upon the monies



derived by the Defendants by means of the above-described actions.

**WHEREFORE**, International Union of Operating Engineers Local 542 demands that judgment be entered in its favor and against Defendants, in an amount to be determined at trial, including but not limited to costs, attorneys' fees, and such other relief deemed just and appropriate by this Court.

**COUNT V**  
**INTERNATIONAL UNION OF OPERATING ENGINEERS LOCAL 542**  
**v.**  
**MALLINCKRODT**  
**Unjust Enrichment**

212. Plaintiff hereby incorporates by reference the preceding and following averments as if fully set forth herein and further alleges as follows.

213. This Count alleges unjust enrichment against Mallinckrodt.

214. IUOE Local 542's covered beneficiaries received direct shipments of Acthar from Mallinckrodt via its exclusive distribution mechanism established with Express Scripts. In exchange for such Acthar, IUOE Local 542 made direct payments to Express Scripts for the benefit of Mallinckrodt. Indeed, such payments were transferred by Express Scripts to Mallinckrodt pursuant to an understanding between the two that the total amount would be forwarded to Mallinckrodt, less a certain amount previously agreed to by Mallinckrodt and Express Scripts. The amount charged by Mallinckrodt for Acthar was the amount paid by Local 542 pursuant to its agreement with Express Scripts.

215. The amounts paid by IUOE Local 542 were valuable to Mallinckrodt and Mallinckrodt was unjustly enriched by such direct payments, in that, the reimbursement rates charged by Mallinckrodt at extremely high prices with inequitable discounts were valuable and beneficial to Express Scripts.

216. By engaging in the conduct described herein, Mallinckrodt has knowingly obtained benefits from IUOE Local 542, namely, grossly inflated revenue from its direct involvement in coordinating all aspects of IUOE Local 542's receipt of and payments for Acthar, under circumstances such that it would be inequitable and unjust for Mallinckrodt to retain such benefits.

217. By engaging in the unlawful conduct described herein, Mallinckrodt has been knowingly enriched by the amount charged for Acthar over and above what it could have charged in a competitive market, wherein Express Scripts would have used its market power to extract lower prices from Mallinckrodt in fulfillment of its obligation to contain costs, and what it could have charged if it had engaged in appropriate cost containment measures.

218. Mallinckrodt, by working with Express Scripts in maintaining and enhancing its monopoly, and its exercise of monopoly power through increasing prices over a decade, and engaging in other unlawful acts and practices, Mallinckrodt was able to extract exorbitant revenue from IUOE Local 542 beyond what it could have received in the absence of such unlawful conduct. This conduct violated state consumer fraud and antitrust laws, as well as the common law of Pennsylvania, and, as such, interfered with the legally protected interests of IUOE Local 542.

219. IUOE Local 542 is therefore entitled to an award of compensatory damages in an amount to be determined at trial, or the imposition of a constructive trust upon the monies derived by the Defendants by means of the above-described actions.

**WHEREFORE**, International Union of Operating Engineers Local 542 demands that judgment be entered in its favor and against Mallinckrodt, in an amount to be determined at trial, including but not limited to costs, attorneys' fees, and such other relief deemed just and

appropriate by this Court.

**COUNT VI**  
**INTERNATIONAL UNION OF OPERATING ENGINEERS LOCAL 542**  
**v.**  
**EXPRESS SCRIPTS**  
**Breach of Contract**  
**Breach of the ESI PBM Agreement**

220. Plaintiff hereby incorporates by reference the preceding and following averments as if fully set forth herein and further alleges as follows.

221. This Count alleges breach of the ESI PBM Agreement against Express Scripts.

222. By its representations, manifestations of assent, customs and practices, ESI is bound to and by the terms of the ESI PBM Agreement.

223. By the foregoing conduct, specifically ESI's failure to provide cost containment services either through nonfeasance or malfeasance, ESI breached the ESI PBM Agreement, repudiated its obligations under the ESI PBM Agreement, and is in default of the ESI PBM Agreement. Specifically, ESI agreed with Mallinckrodt to inflate the AWP's for Acthar in violation of the letter and spirit of the contract. ESI also diverted monies from Plaintiff that should have been paid as rebates.

224. IUOE Local 542 performed and met all of its obligations under the ESI PBM Agreement to date and has a right to and is entitled to all remedies ascribed to it under the ESI PBM Agreement and Pennsylvania law.

225. IUOE Local 542 has been damaged as a direct and proximate result of ESI's failure to perform under the terms of the ESI PBM Agreement.

**WHEREFORE,** International Union of Operating Engineers Local 542 demands that judgment be entered in its favor and against Express Scripts in an amount to be determined at

trial, including but not limited to costs, attorneys' fees, and such other relief deemed just and appropriate by this Court.

**COUNT VII**  
**INTERNATIONAL UNION OF OPERATING ENGINEERS LOCAL 542**  
**v.**  
**EXPRESS SCRIPTS**  
**Promissory Estoppel**

226. Plaintiff hereby incorporates by reference the preceding and following paragraphs hereof as if fully set forth herein.

227. This Count alleges promissory estoppel against Express Scripts. It charges that ESI's conduct described above constitutes a promise to perform under the terms of the ESI PBM Agreement, and a promise upon which IUOE Local 542 relied upon to its detriment.

228. IUOE Local 542 seeks enforcement of ESI's promise to continue with ESI's obligations under the ESI PBM Agreement.

229. ESI utterly refused and failed to fulfill its representations and promises concerning the terms and obligations under the ESI PBM Agreement, including the promise of cost containment with respect to Acthar.

230. IUOE Local 542 relied on the conduct described above, and in justifiable reliance thereon, and as a direct and proximate result of its reliance thereon, IUOE Local 542 has been damaged.

231. Injustice can be avoided only by enforcing ESI's representations and promises concerning the expectations that it created regarding ESI's obligations under the ESI PBM Agreement, and awarding IUOE Local 542 damages based on ESI's failure to fulfill its representations and promises.

**WHEREFORE**, International Union of Operating Engineers Local 542 demands that judgment be entered in its favor and against Express Scripts in an amount to be determined at trial, including but not limited to costs, attorneys' fees, and such other relief deemed just and appropriate by this Court.

**COUNT VIII**  
**INTERNATIONAL UNION OF OPERATING ENGINEERS LOCAL 542**  
**v.**  
**EXPRESS SCRIPTS**  
**Breach of the Implied Covenant of**  
**Good Faith and Fair Dealing**

232. Plaintiff hereby incorporates by reference the preceding and following averments as if fully set forth herein and further alleges as follows.

233. The general duty of good faith and fair dealing in the performance of a contract is found in the Restatement (Second) of Contracts, Section 205, which provides that "every contract imposes upon each party a duty of good faith and fair dealing in its performance and its enforcement."

234. In Pennsylvania and other states, the duty of good faith is defined as honesty in fact in the conduct or transaction concerned.

235. The duty to perform contractual obligations in good faith applies to the ESI PBM Agreement and requires ESI to use its best efforts to fulfill its promise to provide cost containment services.

236. By failing to provide cost containment for Acthar as set forth herein, specifically agreeing with Mallinckrodt to raise the AWP's for Acthar and agreeing with Mallinckrodt to pay ESI monies that should have been paid as rebates, ESI breached the covenant of good faith and fair dealing.

237. ESI's breach of the covenant of good faith and fair dealing was the direct and proximate result of injury and damages to IUOE Local 542.

**WHEREFORE**, International Union of Operating Engineers Local 542 demands that judgment be entered in its favor and against Express Scripts in an amount to be determined at trial, including but not limited to costs, attorneys' fees, and such other relief deemed just and appropriate by this Court.

**COUNT IX**  
**INTERNATIONAL UNION OF OPERATING ENGINEERS LOCAL 542**  
**v.**  
**EXPRESS SCRIPTS AND MALLINCKRODT**  
**Declaratory and Injunctive Relief**

238. Plaintiff has alleged an interest which, insofar as it contracted directly with Express Scripts, who contracted directly with Mallinckrodt, to supply Acthar. Plaintiff's interest is substantial and immediate insofar as it has already had to pay exorbitant prices for Acthar for 3 patients in 2 years. There is a reasonable likelihood that Plaintiff will have to pay for Acthar in the future, especially given Mallinckrodt's marketing effort to expand Acthar prescriptions into new indications, like rheumatoid arthritis.

239. Thus, Plaintiff has alleged a real, actual controversy with Defendants that requires immediate attention. The public has already shown an interest in the Acthar lawsuit being litigated in Rockford, Illinois. Thus, Plaintiff's request for declaratory and injunctive relief does not seek merely an abstract or advisory opinion.

240. Plaintiff hereby requests that the acts and practices set forth herein be declared unlawful under the UTPCPL and/or the common law of negligent misrepresentation, regardless of the quantum of damages suffered individually by Plaintiff, the precise calculation of which will have to await discovery. This will inure to the benefit of Plaintiff, its beneficiaries, the

members of Plaintiff's coalition and self-funded payors elsewhere who have paid, are paying, or will pay in the future for Acthar.

241. Plaintiff also requests the issuance of an injunction to enjoin Mallinckrodt from conspiring and agreeing with Express Scripts through an exclusive arrangement to raise and fix the prices of Acthar above competitive levels. The injunction should also require to dial back the Acthar placing to a level that more accurately reflects the value, or lack thereof, that Express Scripts only first conceded in 2017.

242. An injunction is needed to prevent immediate and irreparable harm that cannot be compensated adequately by damages. Plaintiff will be irreparably harmed if an injunction does not timely issue because patients are put at risk as payors like Plaintiff are forced to decide about whether to cover all the indications for which Mallinckrodt is marketing Acthar. Further, because multiple, individual actions would be required to bring about what one injunction in this action could accomplish, there is an inadequate legal remedy. Plaintiff has no adequate remedy at law to prevent Defendants from furthering acting to harm itself and its patient-beneficiaries due to the unchecked nature of their monopolistic pricing decisions, which have been demonstrated to be far above any reasonable "value" assessment.

243. Greater injury would result from refusing the injunction than from granting it, as patients and payors like Plaintiff will continue to be threatened by new prescriptions of Acthar at exorbitant price levels, threatening patient care. The issuance of an injunction will not substantially harm Express Scripts, because lower, value-based pricing is what Express Scripts claims to provide as part of its PBM services. Mallinckrodt will continue to sell Acthar, if fact likely more Acthar, if the price were lowered.

244. The injunction will properly restore the parties to where they were before the exclusive arrangement was entered between Defendants.

245. Plaintiff has a clear right to relief and is likely to prevail on the merits, in light of the success of the FTC and Retrophin lawsuits which preceded this case and from which this case emanated, both of which Mallinckrodt chose to settle rather than fight.

246. The injunction, as will be framed in an appropriate motion to the court, will be reasonably suited to abate the offending activity only.

247. The public interest will not be adversely affected by the injunction. To the contrary, the public interest will be served by stopping the price gouging of drug companies, like Mallinckrodt, and forcing PBMs like Express Scripts to do their jobs with respect to specialty drugs.

248. All the requisite elements for issuance of an injunction have been, and will be, met.

### **PRAYER FOR RELIEF**

WHEREFORE, International Union of Operating Engineers Local 542 requests the Court to enter the following relief:

- a. Declare unlawful the acts and practices alleged herein, enjoin the Defendants from committing the acts alleged herein, and restore the status quo before the unlawful conduct took place;
- b. Enter judgment against all Defendants for the violations alleged herein;
- c. Award the actual damages incurred by Plaintiff as a result of the wrongful acts complained of, along with pre-judgment and post-judgment interest at the maximum rate allowed by law;
- d. Award statutory damages set forth herein under the statutory claims alleged;



- e. Award treble damages or multiple damages by operation of law;
- f. Award punitive damages;
- g. Award Plaintiff the costs of this action, including reasonable attorney's fees, and, where applicable, expert fees; and
- h. Award such other and further relief as the Court may deem just and appropriate.

**JURY DEMAND**

Plaintiff demands a trial by jury of all issues so triable in this cause.

Respectfully submitted,

Dated: August 27, 2018

By: s/ Donald E. Haviland, Jr.  
Donald E. Haviland, Jr.  
*haviland@havilandhughes.com*  
William H. Platt II  
*platt@havilandhughes.com*  
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Haviland Hughes  
201 South Maple Avenue, Suite 110  
Ambler, PA 19002  
Phone: (215) 609-4661  
Fax: (215) 392-4400

*Counsel for Plaintiff,  
International Union of Operating  
Engineers Local 542*

# EXHIBIT A

**H.P. Acthar® GEL**  
(repository corticotropin injection) 80 U/mL

**FAX: 1-877-937-2284**

**Acthar Start Form**

Please complete Start Form and fax toll-free

TEL: 1-888-435-2284

Monday through Friday (8:00 am to 9:00 pm EST)  
Saturday (9:00 am to 2:00 pm)

## 1. PATIENT INFORMATION

Patient has been notified of referral ☐ YES ☐ NO

PATIENT FIRST NAME	PATIENT MIDDLE INITIAL	PATIENT LAST NAME	DATE OF BIRTH	GENDER
HOME ADDRESS		CITY	STATE	ZIP
SHIPPING ADDRESS (IF NOT HOME ADDRESS)		CARE OF (IF NOT ADDRESSED TO PATIENT)	CITY	STATE ZIP
HOME PHONE	MOBILE	OK TO TEXT	BEST TIME TO CALL	PREFERRED LANGUAGE IF NOT ENGLISH
EMAIL ADDRESS	PATIENT REPRESENTATIVE	RELATIONSHIP	TELEPHONE	

## 2. INSURANCE INFORMATION (PLEASE INCLUDE COPIES OF CARDS)

PHARMACY BENEFITS	SUBSCRIBER ID #	GROUP #	TEL #
PRIMARY MEDICAL INSURANCE	POLICY HOLDER	RELATIONSHIP	SUBSCRIBER ID # GROUP # TEL #

## 3. HEALTHCARE PROVIDER (HCP) INFORMATION

HCP FIRST NAME	HCP LAST NAME	HCP MIDDLE INITIAL	NPI #	GROUP NPI # (IF APPLICABLE)	STATE LICENSE #
SPECIALTY: <input type="checkbox"/> NEPHROLOGY <input type="checkbox"/> NEUROLOGY <input type="checkbox"/> PULMONOLOGY <input type="checkbox"/> RHEUMATOLOGY <input type="checkbox"/> OPHTHALMOLOGY <input type="checkbox"/> OTHER _____ IF OTHER PLEASE INDICATE					
FACILITY NAME	TELEPHONE	FAX			
ADDRESS	CITY	STATE	ZIP		
OFFICE CONTACT NAME	CONTACT TELEPHONE	EMAIL ADDRESS	PREFERRED METHOD OF COMMUNICATION		

## 4. PRESCRIPTION: H.P. ACTHAR® GEL

NDC# 63004-8710-1 5 mL multidose vial containing 80 USP units per mL

**PRIMARY DIAGNOSIS:** \_\_\_\_\_ **ICD-10:** \_\_\_\_\_

INITIATE PATIENT WITH:  
☐ UNITS  
 DOSE: \_\_\_\_\_ ☐ ML SCHEDULE/FREQUENCY: \_\_\_\_\_ QUANTITY OF 5 ML MULTIDOSE VIALS: \_\_\_\_\_ REFILLS: \_\_\_\_\_ ROUTE OF ADMINISTRATION: ☐ INTRAMUSCULAR ☐ SUBCUTANEOUS  
 ADDITIONAL SPECIAL INSTRUCTIONS, OR TAPER DOSE, IF APPLICABLE: \_\_\_\_\_ ALLERGIES: \_\_\_\_\_  
 SUPPLIES:  
 SYRINGE SIZE: ☐ 1 mL ☐ 3 mL ☐ Other size \_\_\_\_\_ QUANTITY: \_\_\_\_\_ NEEDLE SIZE: ☐ 20 g needle, 1 inch ☐ 23 g needle, 1 inch ☐ 25 g needle, 1 inch ☐ 25 g needle, 5/8 inch ☐ (other): \_\_\_\_\_ QUANTITY: \_\_\_\_\_  
 PATIENT WEIGHT (FOR WEIGHT-BASED DOSING ONLY): \_\_\_\_\_ SUPPLY REFILLS: \_\_\_\_\_ SHARPS CONTAINER: \_\_\_\_\_ OTHER SUPPLIES: \_\_\_\_\_

## HOME INJECTION TRAINING SERVICES (HITS)

By initialing here (original required) I request that company-funded HITS services be arranged for my patient. I understand that HITS is for one instruction visit only and NOT a home health nursing service. I also understand that all reasonable efforts will be made to schedule the HITS training visit within 24 hours of the patient's receipt of drug shipment.

INITIALS \_\_\_\_\_ DATE \_\_\_\_\_

## 5. PRESCRIPTION, CONSENT AND STATEMENT OF MEDICAL NECESSITY: HCP SIGNATURE REQUIRED

I certify that H.P. Acthar® Gel is medically necessary for this patient and that I have reviewed this therapy with the patient and will be monitoring the patient's treatment. I verify that the patient and healthcare provider information on this enrollment form is complete and accurate to the best of my knowledge. I understand that I must comply with my practicing state's specific prescription requirements such as, e-prescribing, state specific prescription form, fax language, etc. Non-compliance of state specific requirements could result in outreach to me by the dispensing pharmacy.

I authorize United BioSource Corporation ("UBC"), the current operator of the Acthar Support and Access Program ("Program"), and other designated operators of the program, to perform a preliminary assessment of benefit verification for this patient and furnish information requested by the patient's insurer that is available on this form. I understand that insurance verification is ultimately the responsibility of the provider and third-party reimbursement is affected by a variety of factors. While UBC strives to provide accurate information, they and Mallinckrodt make no representations or warranties as to the accuracy of the information provided.

I understand that representatives from the Program or UBC may contact me or my patient for additional information relating to this prescription. I acknowledge and agree that the designated specialty pharmacy receive this prescription via a designated third party, the Program and that no additional confirmation of receipt of prescription is required by the designated specialty pharmacy.

**HCP Prescriber Signature - Please sign ONE LINE below**

DISPENSE AS WRITTEN	DATE	SUBSTITUTIONS ALLOWED	DATE
Prescriber signature required to consent and validate prescriptions. Prescriber attests that this is her/his signature. NO STAMPS. By signing, I certify that the above is medically necessary.			



For Patient: \_\_\_\_\_ DOB: \_\_\_\_\_

**6. DIAGNOSIS AND MEDICAL INFORMATION****Diagnosis**

Please select diagnosis and responses to associated questions

**Ankylosing spondylitis****Dermatomyositis****Infantile spasms**

Has diagnosis been confirmed by EEG?

☐ YES ☐ NO

Patient's weight: \_\_\_\_\_

Requested drug delivery date: \_\_\_\_\_

**Multiple sclerosis**

Is Acthar to be used to treat an acute exacerbation?

☐ Exacerbation ☐ Other \_\_\_\_\_ Must check one

Onset of acute exacerbation Date: \_\_\_\_\_

**Optic neuritis****Polymyositis****Proteinuria in nephrotic syndrome**

Please indicate etiology:

Focal segmental glomerular sclerosis (FSGS)

IgA nephropathy (IgAN)

Lupus nephritis

Membranous nephropathy (MN)

Other: \_\_\_\_\_

**Psoriatic arthritis****Rheumatoid arthritis****Sarcoidosis****Systemic lupus erythematosus**

Is Acthar to be used to treat an acute exacerbation?

☐ YES ☐ NO Must check one**Lupus nephritis?**☐ YES ☐ NO**Uveitis****Other diagnosis** \_\_\_\_\_**7. HISTORY OF CORTICOSTEROID USE (IF APPLICABLE) PLEASE ADD DETAILS IN SECTION 8 BELOW**

Please check all that apply

**A corticosteroid was tried with the following response(s):**

Corticosteroid use failed, but same response not expected with Acthar

Patient hypersensitive or allergic to corticosteroids

Patient intolerant to corticosteroids

Other: \_\_\_\_\_

OR

**A corticosteroid was not tried due to the following response(s):**

Corticosteroid use is contraindicated for this patient

Intravenous access is not possible for this patient

Patient has known intolerance to corticosteroids

Other: \_\_\_\_\_

**8. CONCURRENT MEDICATIONS****9. RELEVANT TREATMENT HISTORY (INCLUDING RECENT STEROID HISTORY)**

Therapy Name	Dose	Start Date	Stop Date (if applicable)	Explain Outcome With Detail (ex. type of outcome)

(Attach additional pages as necessary)

**OTHER RELEVANT CLINICAL INFORMATION****HCP SIGNATURE: REQUIRED FOR DOCUMENTATION**

NAME

SIGNATURE

DATE



**H.P. Acthar<sup>®</sup> GEL**  
(repository corticotropin injection) 80 U/mL

For completion by patient or their representative

Patient Name: \_\_\_\_\_ DOB: \_\_\_\_\_

**10. PATIENT AUTHORIZATION(S)**

**For Patient Review and Completion. If patient is not available, authorization will be obtained from patient by Acthar Support and Access Team upon receipt of referral.**

By signing this authorization, I authorize my physician(s), my health insurance company, my pharmacy providers and Mallinckrodt ARD Inc., the distributor of Acthar ("Mallinckrodt"), and its agents, authorized designees and contractors, including Mallinckrodt reimbursement support personnel and United BioSource Corporation ("UBC") or any other operator of the Acthar Support and Access Program on behalf of Mallinckrodt (collectively, "Designated Parties"), to use and disclose to other Designated Parties health information relating to my medical condition, treatment, and insurance coverage (my "Health Information") in order for them to (1) provide certain services to me, including reimbursement and coverage support, patient assistance and access programs, medication shipment tracking, and home injection training, (2) provide me with support services and information associated with my Acthar therapy, (3) for internal business purposes, such as for marketing research, internal financial reporting and operational purposes, and (4) to carry out the Designated Parties' respective legal responsibilities.

Once my Health Information has been disclosed to the Designated Parties, I understand that it may be re-disclosed by them and no longer protected by federal and state privacy laws. However, the Designated Parties agree to protect my Health Information by using and disclosing it only for the purposes detailed in this authorization or as permitted or required by law.

I understand that I may refuse to sign this authorization and that my physician and pharmacy will not condition my treatment on my agreement to sign this authorization form, and my health plan or health insurance company will not condition payment for my treatment, insurance enrollment or eligibility for insurance benefits on my agreement to sign this authorization form. I understand that my pharmacies and other Designated Parties may receive payment in connection with the disclosure of my Health Information as provided in this authorization. I understand that I am entitled to receive a copy of this authorization after I sign it.

I may revoke (withdraw) this authorization at any time by mailing a letter to Acthar Support and Access, 255 Technology Park, Lake Mary, FL 32746. Revoking this authorization will end further disclosure of my Health Information to Designated Parties by my pharmacy, physicians and health insurance company when they receive a copy of the revocation, but it will not apply to information they have already disclosed to the Designated Parties based on this authorization. I also know I may cancel my enrollment in a patient support program at any time in writing by contacting Mallinckrodt via fax at 877-937-2284.

This authorization is in effect for 1 year or until the conclusion of any ongoing coverage support, whichever is longer, once I have signed it unless I cancel it before then.

PATIENT NAME OR LEGAL REPRESENTATIVE	PATIENT SIGNATURE	IF LEGAL REPRESENTATIVE, RELATIONSHIP TO PATIENT	DATE
--------------------------------------	-------------------	--	------

I authorize Mallinckrodt and its agents to receive, use, and disclose my health information relating to my medical condition, treatment, insurance coverage, and contact information from me, my healthcare providers, my pharmacies, and my health insurance company in order to (1) contact me about participation in Acthar patient programs, (2) provide me with educational or other informational materials, (3) administer its education and other patient-related programs, (4) conduct surveys that request my feedback, and (5) for Mallinckrodt to carry out its legal responsibilities in connection with these education and support programs. I agree to let Mallinckrodt or its agents contact me in the future about these offerings. Once my health information has been disclosed to the education, informational and/or support program I choose to participate in, I understand that it may be redisclosed by Mallinckrodt or its agents, and they are authorized to use or disclose this information in the manner described here and as permitted by this authorization or as otherwise permitted or required by law, and that federal and state privacy laws may no longer protect the information. However, Mallinckrodt and its agents agree to protect my health information by using and disclosing it only for the purposes described in this authorization or as permitted or required by law. This authorization will remain in effect until I cancel it which I may do so at any time by contacting Mallinckrodt via fax at 877-937-2284. Cancelling this authorization will end further use or disclosure of my health information by Mallinckrodt or its agents (except to the extent that such parties took actions based on this authorization prior to my revocation). If I withdraw my permission, I know that this means I may no longer receive information on supplemental education or support programs. Once I withdraw my permission, no new information will be disclosed to Mallinckrodt or its agents, but Mallinckrodt and its agents may continue to use the information that was collected before I withdrew my permission as permitted by this authorization or as otherwise permitted or required by law. I may request a copy of this signed authorization.

PATIENT NAME OR LEGAL REPRESENTATIVE	PATIENT SIGNATURE	IF LEGAL REPRESENTATIVE, RELATIONSHIP TO PATIENT	DATE
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**INDICATIONS AND USAGE**

- **Infantile spasms:** H.P. Acthar Gel (repository corticotropin injection) is indicated as monotherapy for the treatment of infantile spasms in infants and children under 2 years of age
- **Multiple Sclerosis:** H.P. Acthar Gel (repository corticotropin injection) is indicated for the treatment of acute exacerbations of multiple sclerosis in adults. Controlled clinical trials have shown H.P. Acthar Gel to be effective in speeding the resolution of acute exacerbations of multiple sclerosis. However, there is no evidence that it affects the ultimate outcome or natural history of the disease
- **Rheumatic Disorders:** As adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in: psoriatic arthritis, rheumatoid arthritis, including juvenile rheumatoid arthritis (selected cases may require low-dose maintenance therapy), ankylosing spondylitis
- **Collagen Diseases:** During an exacerbation or as maintenance therapy in selected cases of: systemic lupus erythematosus, systemic dermatomyositis (polymyositis)
- **Dermatologic Diseases:** Severe erythema multiforme, Stevens-Johnson syndrome
- **Allergic States:** Serum sickness
- **Ophthalmic Diseases:** Severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa such as: keratitis, iritis, iridocyclitis, diffuse posterior uveitis and choroiditis, optic neuritis, chorioretinitis, anterior segment inflammation
- **Respiratory Diseases:** Symptomatic sarcoidosis
- **Edematous State:** To induce a diuresis or a remission of proteinuria in the nephrotic syndrome without uremia of the idiopathic type or that due to lupus erythematosus

**IMPORTANT SAFETY INFORMATION****CONTRAINDICATIONS**

- Acthar should never be administered intravenously
- Administration of live or live attenuated vaccines is contraindicated in patients receiving immunosuppressive doses of Acthar
- Acthar is contraindicated where congenital infections are suspected in infants
- Acthar is contraindicated in patients with scleroderma, osteoporosis, systemic fungal infections, ocular herpes simplex, recent surgery, history of or the presence of a peptic ulcer, congestive heart failure, uncontrolled hypertension, primary adrenocortical insufficiency, adrenocortical hyperfunction or sensitivity to proteins of porcine origins

**WARNINGS AND PRECAUTIONS**

- The adverse effects of Acthar are related primarily to its steroidogenic effects
- Acthar may increase susceptibility to new infection or reactivation of latent infections
- Suppression of the hypothalamic-pituitary-axis (HPA) may occur following prolonged therapy with the potential for adrenal insufficiency after withdrawal of the medication. Adrenal insufficiency may be minimized by tapering of the dose when discontinuing treatment. During recovery of the adrenal gland patients should be protected from the stress (e.g. trauma or surgery) by the use of corticosteroids. Monitor patients for effects of HPA suppression after stopping treatment
- Cushing's Syndrome may occur during therapy but generally resolves after therapy is stopped. Monitor patients for signs and symptoms
- Acthar can cause elevation of blood pressure, salt and water retention, and hypokalemia. Blood pressure, sodium and potassium levels may need to be monitored
- Acthar often acts by masking symptoms of other diseases/disorders. Monitor patients carefully during and for a period following discontinuation of therapy
- Acthar can cause GI bleeding and gastric ulcer. There is also an increased risk for perforation in patients with certain gastrointestinal disorders. Monitor for signs of bleeding
- Acthar may be associated with central nervous system effects ranging from euphoria, insomnia, irritability, mood swings, personality changes, and severe depression, and psychosis. Existing conditions may be aggravated
- Patients with comorbid disease may have that disease worsened. Caution should be used when prescribing Acthar in patients with diabetes and myasthenia gravis
- Prolonged use of Acthar may produce cataracts, glaucoma and secondary ocular infections. Monitor for signs and symptoms
- Acthar is immunogenic and prolonged administration of Acthar may increase the risk of hypersensitivity reactions. Neutralizing antibodies with chronic administration may lead to loss of endogenous ACTH activity
- There is an enhanced effect in patients with hypothyroidism and in those with cirrhosis of the liver
- Long-term use may have negative effects on growth and physical development in children. Monitor pediatric patients
- Decrease in bone density may occur. Bone density should be monitored for patients on long-term therapy
- Pregnancy Class C: Acthar has been shown to have an embryocidal effect and should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus

**ADVERSE REACTIONS**

- Common adverse reactions for Acthar are similar to those of corticosteroids and include fluid retention, alteration in glucose tolerance, elevation in blood pressure, behavioral and mood changes, increased appetite and weight gain
- Specific adverse reactions reported in IS clinical trials in infants and children under 2 years of age included: infection, hypertension, irritability, Cushingoid symptoms, constipation, diarrhea, vomiting, pyrexia, weight gain, increased appetite, decreased appetite, nasal congestion, acne, rash, and cardiac hypertrophy. Convulsions were also reported, but these may actually be occurring because some IS patients progress to other forms of seizures and IS sometimes mask other seizures, which become visible once the clinical spasms from IS resolve

Other adverse events reported are included in the full Prescribing Information.

Please see accompanying full Prescribing Information.

# EXHIBIT B



Q U E S T C O R

## URGENT PRODUCT ALERT H.P. Acthar® Gel

July 2, 2007

Dear Healthcare Professional,

As you know, H.P. Acthar® Gel (repository corticotropin injection) plays a critical role in many inpatient and outpatient treatment regimens. **Effective August 1, 2007, Acthar Gel (NDC # 63004-7731-1) will be available exclusively through Specialty Pharmacy Distribution.** Acthar Gel will no longer be available from traditional pharmaceutical wholesalers or retail pharmacies. Please be sure to share this information appropriately with your staff and patients.

### **For Hospital Stock Orders**

Beginning July 16, 2007, hospitals should place all stock orders with CuraScript Specialty Distribution (877-599-7748). We suggest that appropriate personnel at your facility contact CuraScript Specialty Distribution (877-599-7748) as soon as possible to establish an account.

### **Planning for Patient Discharge – Outpatient Prescriptions**

Beginning July 16, 2007, when treatment with Acthar Gel is initiated in a hospital setting with the intent to continue after discharge, it is imperative that the outpatient prescription order be placed immediately after treatment initiation to ensure an uninterrupted supply of Acthar Gel at discharge. Beginning July 16, 2007, please contact the following support and access program to get prescriptions filled and for assistance with reimbursement:

#### **Acthar Support & Access Program (ASAP)**

- PHONE: 888-435-2284
- FAX: 877-937-2284

More information and referral forms can be obtained at [www.acthar.com](http://www.acthar.com).

### **Filling Prescriptions**

Please tell your patients currently having Acthar Gel prescriptions filled at retail pharmacies to immediately confirm the pharmacy has stock on hand for their remaining refills. Beginning July 16, 2007, all new Acthar Gel prescriptions should be submitted to the Acthar Support & Access Program (PHONE: 888-435-2284; FAX: 877-937-2284).

Questcor is committed to providing uninterrupted availability of Acthar Gel for patients who critically need it. This change in Acthar Gel distribution and the creation of the Acthar Support & Access Program is an important part of this mission.

Sincerely,

Steve Cartt, Executive Vice President, Corporate Development  
Questcor Pharmaceuticals



# EXHIBIT C

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF COLUMBIA**

FEDERAL TRADE COMMISSION,  
the States of ALASKA, MARYLAND,  
NEW YORK, TEXAS, and  
WASHINGTON,

Case Number:

Plaintiffs,

v.

MALLINCKRODT ARD INC.,  
formerly known as QUESTCOR  
PHARMACEUTICALS, INC., a  
California corporation, and  
MALLINCKRODT PLC, an Irish  
public limited company,

Defendants.

**COMPLAINT FOR INJUNCTIVE AND OTHER EQUITABLE RELIEF**

Plaintiffs, the Federal Trade Commission (“FTC”) and the states of Alaska, Maryland, New York, Texas, and Washington (collectively, the “Plaintiff States”), by their designated attorneys, petition this Court, pursuant to Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), Section 16 of the Clayton Act, 15 U.S.C. § 26, and the relevant state laws—Alaska Stat. §§ 45.50.501, 45.50.577 and 45.50.580, Md. Code Ann. Com. Law § 11-209, NY Gen. Bus. Law § 340 et seq., New York Executive Law 63(12), Tex. Bus. & Com. Code Ann. § 15.20, and Wash. Rev. Code § 19.86.080—for permanent injunctive and other equitable relief against Defendants Mallinckrodt ARD Inc., formerly known as Questcor Pharmaceuticals, Inc. (“Questcor”), and Mallinckrodt plc (“Mallinckrodt”) to undo and prevent their unfair methods of competition in or affecting commerce in violation of Section 5(a) of the FTC Act, 15 U.S.C. § 45(a), and acts of monopolization in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2, and various state laws as identified in Count III, and state for their complaint as follows:

### **I. Nature of the Case**

1. Through its anticompetitive conduct, Questcor has extinguished a nascent competitive threat to its monopoly. Questcor's H.P. Acthar Gel ("Acthar") is the only therapeutic adrenocorticotrophic hormone ("ACTH") product sold in the United States. ACTH is the standard of care for infantile spasms ("IS"), a rare but extremely serious disorder involving seizures within the first two years of life. It is also used to treat nephrotic syndrome ("NS")—a kidney disorder whose largest single cause is idiopathic membranous nephropathy ("IMN")—as well as other disorders.

2. Questcor acquired Acthar from Aventis Pharmaceuticals, Inc. in 2001 for \$100,000 plus modest royalties. At that time, the price of Acthar was \$40 per vial. Questcor has since raised Acthar's price to over \$34,000 per vial—an 85,000% increase.

3. A course of Acthar treatment for IS requires multiple vials and can cost well over \$100,000.

4. For other indications, as the CEO of Mallinckrodt has admitted, Acthar is in many cases "the only alternative for patients that have tried and failed on many other therapies."

5. Questcor's Acthar price increases have persisted and proved very profitable. Acthar's U.S. revenues in 2015 exceeded \$1 billion.

6. In Europe, Canada, and other parts of the world, doctors treat patients suffering from these same conditions with Synacthen Depot ("Synacthen"), a synthetic ACTH drug. Although Acthar is a natural ACTH drug derived from the pituitary glands of pigs, Acthar and Synacthen have very similar biological activities and pharmacological effects. As the Canadian product monograph for Synacthen reads, "SYNACTHEN . . . exhibits the same activity as natural ACTH with regard to all its biological activities." Questcor considers the drugs so

similar that it submitted Synacthen information to support its application to the U.S. Food and Drug Administration (“FDA”) to expand the label indications for Acthar and cited Synacthen studies in its Acthar marketing materials.

7. Until June 2013, Novartis AG (“Novartis”) marketed and sold Synacthen abroad.

8. In 2011, Novartis decided to sell the rights to market Synacthen in the United States. For years, Questcor had viewed Synacthen as a significant potential competitive threat to Acthar. In June 2013, Questcor outbid other companies to acquire the U.S. rights to Synacthen. Questcor’s participation in the bidding process was a defensive move designed to protect its monopoly over ACTH drugs in the United States. By acquiring Synacthen, Questcor harmed competition by preventing another bidder from trying to develop the drug and launch it in the United States to challenge Questcor’s monopoly over ACTH drugs.

## **II. The Parties**

9. Plaintiff FTC is an administrative agency of the United States, established, organized, and existing pursuant to the FTC Act, 15 U.S.C. §§ 41 et seq., with its principal offices at 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580. The FTC is vested with the authority and responsibility for enforcing, inter alia, Section 5 of the FTC Act, 15 U.S.C. § 45, and is authorized under Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), to initiate court proceedings to seek injunctive relief to prevent or remedy violations of any law the FTC enforces and to seek equitable remedies.

10. The Attorneys General of the Plaintiff States are the chief legal officers for their respective states. They are granted authority under federal antitrust law to bring actions for injunctive relief and under the laws of their respective states to bring actions to ensure compliance with their state laws and to enjoin violations of state law.

11. Defendant Mallinckrodt is an Irish public limited company headquartered in Staines-upon-Thames, United Kingdom, with its U.S. headquarters in St. Louis, Missouri.

12. Mallinckrodt acquired Questcor on August 14, 2014, for approximately \$5.9 billion. At that time, Acthar was the only drug product sold by Questcor. With Mallinckrodt's acquisition, Questcor became a wholly owned subsidiary of Mallinckrodt and subsequently changed its corporate name from Questcor Pharmaceuticals, Inc. to Mallinckrodt ARD Inc.

13. Defendant Mallinckrodt ARD Inc. is a biopharmaceutical company incorporated in California and headquartered in Anaheim, California. The company manufactures and sells Acthar in the United States.

### **III. Jurisdiction and Venue**

14. This Court has subject matter jurisdiction over this action pursuant to 15 U.S.C. §§ 45(a) and 53(b), and 28 U.S.C. §§ 1331, 1337(a), and 1345.

15. This Court has personal jurisdiction over Defendants pursuant to 15 U.S.C. § 53(b) because each Defendant has the requisite constitutional contacts with the United States of America.

16. In conjunction with the Commission, the Plaintiff States also bring this action for civil penalties and injunctive relief under Section 16 of the Clayton Act, 15 U.S.C. § 26, Alaska Stat. §§ 45.50.501, 45.50.551, 45.50.577 and 45.50.580, Md. Code Ann. Com. Law § 11-209, NY Gen. Bus. Law § 340 et seq., New York Executive Law 63(12), Tex. Bus. & Com. Code Ann. § 15.20, and Wash. Rev. Code § 19.86.080. All claims under federal and state law are based upon a common nucleus of operative fact, and the entire action commenced by this Complaint constitutes a single case that would ordinarily be tried in one judicial proceeding. This Court has jurisdiction over the non-federal claims under 28 U.S.C. § 1367(a), as well as

under principles of pendent jurisdiction.

17. Venue in this district is proper under Section 13(b)(2) of the FTC Act, 15 U.S.C. § 53(b), 15 U.S.C. § 22, and 28 U.S.C. § 1391(b), (c), and (d). Each Defendant resides, transacts business, or is found in this district.

18. Questcor and Mallinckrodt are, and at all relevant times have been, engaged in commerce or in activities affecting “commerce” as defined in Section 4 of the FTC Act, 15 U.S.C. § 44, and Section 1 of the Clayton Act, 15 U.S.C. § 12. Defendants also are, and at all relevant times have been, engaged in commerce in each of the Plaintiff States.

19. Questcor and Mallinckrodt are, and at all times relevant have been, a “corporation,” as defined in Section 4 of the FTC Act, 15 U.S.C. § 44.

#### **IV. Questcor Possesses Monopoly Power With Acthar**

20. Questcor has exercised, and continues to exercise, monopoly power in the United States with Acthar. The supracompetitive prices that Questcor charges for Acthar and its restriction of Acthar’s output are direct evidence of this monopoly power. Questcor’s monopoly power is also established by indirect evidence, which shows that Acthar holds a dominant share of the relevant market for ACTH drugs in the United States. That market is and has been characterized by substantial barriers to entry.

##### **A. Direct Evidence of Acthar’s Monopoly Power**

21. Questcor has repeatedly and profitably raised Acthar’s price substantially over the last decade. On August 27, 2007, Questcor increased the price of Acthar more than 1,300% overnight, from \$1,650 to \$23,269 per vial, causing its revenues to increase dramatically and its profits to soar. Additionally, Questcor has taken significant and profitable increases on eight occasions since 2011, pushing the price up another 46% to its current \$34,034 per vial. Acthar

net sales grew from \$218 million in 2011 to more than \$1 billion in 2015.

22. Each alternative bidder expected to profitably sell Synacthen at a price well below Acthar's price, demonstrating that Acthar is currently priced at a supracompetitive level. The lower prices that would prevail in a duopoly market containing Acthar and Synacthen show that Acthar is currently extracting substantial monopoly rents.

23. Questcor restricts the output of Acthar by charging an extraordinarily high price, forcing third-party payers (e.g., health insurers) to limit Acthar's usage to the narrowest possible group of patients—those for whom no effective therapeutic alternatives exist. When Questcor implemented its 1,300% price increase in 2007, payers implemented formulary restrictions on Acthar. Most payers continue to impose stringent restrictions on Acthar. By setting a supracompetitive price and restricting the output of Acthar, Questcor has reduced market-wide output below competitive levels.

B. Indirect Evidence of Acthar's Monopoly Power

24. The relevant product market is ACTH drugs.

25. Questcor has encountered no competitive constraint on its ability to repeatedly and profitably increase Acthar's price and earn extremely high margins. Questcor does not set the price of Acthar in reference to the price of any of the other drugs that are prescribed to treat the same indications that Acthar treats. Acthar is priced significantly higher than non-ACTH drugs used to treat the same indications.

26. Acthar is indicated for the treatment of IS. Pediatric neurologists consider ACTH the gold standard treatment for IS. Other market participants—including doctors, third-party payers, and pharmaceutical companies (including Questcor)—agree. Treating an infant with IS using Acthar can cost more than \$100,000. The only other treatment that is FDA-approved for

IS is Sabril, which has a completely different molecular structure and mechanism of action than Acthar and is used primarily in a discrete subset of IS patients. At approximately \$25,000 per course of treatment, Sabril costs substantially less than Acthar. Although some doctors prescribe other treatments for a minority of IS patients, those treatments work differently than Acthar and are not substitutes for Acthar. Neither the price of Sabril nor the prices of other IS treatments have affected Acthar's pricing, and none of these other treatments constrains the price of Acthar.

27. Acthar is indicated for the treatment of IMN. Because of its high price, Acthar typically is prescribed only as a last-line therapy to treat IMN. A course of Acthar treatment for IMN can cost hundreds of thousands of dollars. Nephrologists prescribe low-cost, generic oncology agents or immunosuppressants as first and second-line therapies to treat most IMN patients. If those therapies fail or cannot be tolerated, some doctors may prescribe the drug Rituxan, whose costs can range from approximately \$13,000 to \$40,000 for a course of treatment. Because Acthar functions differently than any of these other therapies, doctors and payers do not consider these therapies substitutes for Acthar, and the price of Acthar is not constrained by any of these treatments.

28. Acthar is indicated for the treatment of other indications, including MS flare-ups and rheumatology conditions. For these indications, the price of Acthar is unconstrained by other drugs used to treat those conditions.

29. Even if Synacthen were approved by the FDA for only one of Acthar's indications, Synacthen would compete directly with Acthar and would be properly included in the relevant market. Synacthen is pharmacologically very similar to Acthar, as the active ingredient in both drugs is an ACTH molecule. Many doctors would prescribe Synacthen as a substitute for Acthar, and many payers would require its use in place of Acthar. Each alternative



purchaser of the Synacthen assets expected to compete head-to-head with Acthar and to take a substantial amount of Acthar's business with both on- and off-label sales.

30. The relevant geographic market is the United States. FDA approval is required to market pharmaceuticals to U.S. consumers. As a result, drugs sold outside of the United States are not viable competitive alternatives for U.S. consumers, even in the event of a significant price increase for ACTH drugs available in the United States.

31. Acthar has a 100% share of the market for ACTH drugs in the United States. No other ACTH drug is FDA-approved for therapeutic use.

32. The U.S. ACTH market is characterized by high barriers to entry. Developing a long-acting, depot-injection formulation of a drug product containing ACTH (natural or synthetic) that is stable, safe, and effective would require significant time, cost, and effort, with no guarantee of success. The requirements for entry include sourcing the active pharmaceutical ingredient, formulating a sustained-release depot-injection formulation, scaling production to clinical scale, and successfully conducting clinical trials necessary for FDA approval. Mallinckrodt's CEO has assured investors that Acthar "has significant durability in the marketplace" because "it will be very difficult for this product to be replicated in any way [by] a generic."

#### **V. Questcor Engaged in Anticompetitive Conduct By Acquiring Synacthen**

33. Synacthen posed a threat to Questcor's ACTH drug monopoly, so Questcor intervened when other firms attempted to acquire the U.S. rights to Synacthen from Novartis. Questcor submitted a bid that included substantially more guaranteed money than the other bidders had offered, effectively ending the bidding process. By acquiring Synacthen, Questcor eliminated the possibility that another firm would develop it and compete against Acthar.

A. Synacthen Posed a Nascent Competitive Threat to Acthar

34. Synacthen constituted a nascent competitive threat to Questcor’s ACTH drug monopoly, notwithstanding the significant uncertainty that Synacthen, a preclinical drug, would be approved by the FDA.

35. For years, Questcor viewed Synacthen as a significant potential competitive threat to its monopoly.

36. In 2006, when Questcor decided to pursue an “orphan” (i.e., high) pricing model for Acthar, it recognized the potential threat Synacthen posed to Acthar’s revenue growth.

37. In 2009, Questcor approached Novartis about acquiring Synacthen. At that time, Questcor continued to view Synacthen as a possible future competitor. Unsuccessful in that attempt, Questcor continued to monitor the competitive threat from Synacthen.

38. In 2012, Questcor again concluded that Synacthen posed a threat to Acthar should it be approved for sale in the United States.

39. In 2013, Questcor feared that if another company were to acquire Synacthen and obtain FDA approval, it could decimate its business.

40. But as long as Questcor believed no other firm was seeking to bring Synacthen to the United States, Questcor did not make further attempts to acquire it. Just months before Questcor began pursuing the acquisition of Synacthen, top Questcor officials questioned whether Synacthen would provide any affirmative value to Questcor.

B. Other Bidders Planned to Use Synacthen to Challenge Acthar’s Monopoly

41. Unbeknownst to Questcor at the time, Novartis decided in late 2011 to divest exclusive rights to seek FDA approval for Synacthen and commercialize it in the United States, along with the marketing rights for Synacthen in over thirty-five other countries where the drug

was already approved and sold. Dozens of companies contacted Novartis and expressed interest in acquiring Synacthen. Three firms proceeded through several rounds of negotiations with Novartis, submitted formal offers, and drafted near-final agreements.

42. Each of the three firms planned to develop Synacthen for IS and/or IMN and use Synacthen to compete directly with Acthar. With approval for one or both of these indications, each firm expected to capture a significant share of the U.S. ACTH market from Questcor by pricing Synacthen well below Acthar. Having the requisite pharmaceutical expertise and financing, the three firms independently conducted due diligence, crafted business plans and regulatory approval strategies, and took other affirmative steps in furtherance of developing Synacthen for the U.S. market.

#### C. The Value of the Synacthen Assets

43. The Synacthen assets and related rights provide a proven formulation for a long-acting, depot-injection drug containing synthetic ACTH. The drug product manufactured using the Synacthen formulation has been safely and effectively used to treat patients suffering from IS and other conditions worldwide for decades. The Synacthen assets would therefore facilitate commercializing a synthetic ACTH therapy in the United States.

44. The asset package sold by Novartis included valuable trade secrets, including technical documentation detailing both the precise formulation for the Synacthen drug product and the manufacturing process.

45. In possession of the Synacthen assets, a buyer would not need to create a synthetic ACTH drug formulation de novo, nor would it need to develop from scratch the manufacturing and testing protocols necessary for production of the drug product.

D. Questcor Disrupted the Synacthen Bidding Process

46. In October 2012, Questcor learned that at least one unidentified firm was attempting to acquire Synacthen from Novartis and develop it for the United States. Questcor immediately attempted to reach Novartis and shortly thereafter signed a confidentiality agreement with Novartis and submitted an offer for Synacthen.

47. Novartis negotiated with the three alternative bidders in parallel with Questcor. By the spring of 2013, all three of the alternative bidders had submitted offers for Synacthen, with plans to develop and launch Synacthen in the United States in direct competition with Acthar. At the point where those negotiations left off, each company had exchanged deal terms with Novartis and had submitted a formal offer. The offers by the three alternative bidders were comparable in value and structured similarly, and included an upfront payment, milestone payments upon FDA approval, and significant royalties on U.S. Synacthen sales.

48. Unlike the three alternative bidders, Questcor had only inchoate plans for Synacthen and conducted limited due diligence when it submitted its initial offer to Novartis.

49. On June 11, 2013, Questcor and Novartis entered into a Licensing Agreement, Asset Purchase Agreement, and Supply Agreement (collectively, “the Agreements”), pursuant to which Questcor gained the exclusive rights to develop, market, and sell Synacthen in the United States and over thirty-five other countries. Under the Agreements, Questcor is obligated to pay a minimum of \$135 million, and likely will pay \$300 million to Novartis for Synacthen.

E. Questcor’s Acquisition of Synacthen Harmed Competition

50. Questcor’s strategy to protect its monopoly position with Acthar was successful. But for Questcor’s acquisition of Synacthen, one of the three alternative bidders would have acquired Synacthen and pursued its plan to develop Synacthen for IS and/or IMN to compete

directly with Acthar at a lower price. With the acquisition of Synacthen, Questcor thwarted a nascent challenge to its Acthar monopoly and thereby harmed competition.

51. Questcor claimed that it acquired Synacthen to develop it for new, non-Acthar indications, but given the drugs' similarities, any therapeutic indication that Questcor pursues with Synacthen could have been pursued with Acthar.

52. Fourteen months after acquiring Synacthen, Mallinckrodt acquired Questcor for \$5.9 billion. The vast majority of Questcor's value was attributable to Acthar.

### **COUNT I – Monopolization in Violation of the FTC Act**

53. Plaintiff the FTC re-alleges and incorporates by reference all of the allegations in the above paragraphs.

54. Defendants have, and at all relevant times had, monopoly power in the market for the sale of ACTH drugs in the United States.

55. Disrupting the bidding process for Synacthen and executing a license to the U.S. rights to Synacthen from Novartis eliminated the nascent competitive threat posed by an independently owned Synacthen and is conduct reasonably capable of contributing significantly to Questcor's maintenance of monopoly power.

56. Defendants' acts and practices are anticompetitive in nature and tendency and constitute unfair methods of competition in violation of Section 5(a) of the FTC Act, 15 U.S.C. § 45(a).

### **COUNT II – Monopolization in Violation of the Sherman Act**

57. Plaintiff States re-allege and incorporate by reference all of the allegations in the above paragraphs.

58. Defendants have, and at all relevant times had, monopoly power in the market for

the sale of ACTH drugs in the United States.

59. Disrupting the bidding process for Synacthen and executing a license to the U.S. rights to Synacthen from Novartis eliminated the nascent competitive threat posed by an independently owned Synacthen and is conduct reasonably capable of contributing significantly to Questcor's maintenance of monopoly power.

60. Defendants' acts and practices constitute monopolization in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

### **COUNT III – Supplemental State Law Claims**

61. Plaintiff States re-allege and incorporate by reference all of the allegations in the above paragraphs.

62. The aforementioned practices by Defendants were and are in violation of Alaska's Restraint of Trade Act, Alaska Stat. §§ 45.50.562 et seq., Alaska's Unfair Trade Practices and Consumer Protection Act, Alaska Stat. §§ 45.50.471 et seq., and the common law of Alaska.

63. The aforementioned practices by Defendants were and are in violation of the Maryland Antitrust Act, Md. Code Ann., Com. Law §§ 11-201 et seq.

64. The aforementioned practices by Defendants were and are in violation of New York's antitrust law, the Donnelly Act, New York Gen. Bus. Law §340 et seq., and is proscribed by New York Executive Law 63(12), in that the aforementioned practices constitute illegality and/or illegal acts in the carrying on, conducting, or transacting of business.

65. The aforementioned practices by Defendants were and are in violation of Texas's Free Enterprise and Antitrust Act, Tex. Bus. & Com. Code Ann. §§ 15.01 et seq.

66. The aforementioned practices by Defendants were and are in violation of Washington's Consumer Protection Act, Wash. Rev. Code §§ 19.86 et seq., as proscribed by §

19.86.040, in that the aforementioned practices are unlawful in any part of trade or commerce.

**Prayer for Relief**

WHEREFORE, Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), Section 16 of the Clayton Act, 15 U.S.C. § 26, Alaska Stat. §§ 45.50.501 and 45.50.580, Md. Code Ann. Com. Law § 11-209, New York Gen. Bus. Law §340 et seq., New York Executive Law 63(12), Tex. Bus. & Com. Code Ann. § 15.20, and Wash. Rev. Code § 19.86.080 empower this Court to issue a permanent injunction against violations of the FTC Act and, in the exercise of its equitable jurisdiction, to order ancillary equitable relief to remedy the injury caused by Defendants' violations; therefore, Plaintiffs request that this Court enter final judgment against Defendants Mallinckrodt and Questcor:

1. Adjudging that Defendants' conduct constitutes monopolization in violation of Section 5(a) of the FTC Act, 15 U.S.C. § 45(a),
2. Adjudging that Defendants' conduct constitutes monopolization in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2;
3. Adjudging that Defendants have committed violations of each of the state laws enumerated in Count III;
4. Ordering that Defendants are permanently enjoined from engaging in similar and related conduct in the future;
5. Ordering divestiture and any further actions needed to restore competition lost due to the Defendants' violations;
6. Granting such other equitable relief as the Court finds necessary, including equitable monetary relief, to redress and prevent recurrence of Defendants' violations of Section 5(a) of the FTC Act, Section 2 of the Sherman Act, and the state laws enumerated in Count III,

as alleged herein;

7. Ordering Defendants to pay civil penalties pursuant to Alaska Stat. §§ 45.50.551(b) and 45.50.578(b)(2), Md. Code Ann., Com. Law § 11-209(a)(4), New York Gen. Bus. Law §342-a, Tex. Bus. & Com. Code Ann. §15.20(a), and Rev. Code of Wash. Ann. § 19.86.140; and

8. Awarding the Plaintiff States the costs of this action, including reasonable attorneys' fees and costs, as provided for in the Clayton Act and applicable state law.



Dated: January 18, 2017

Respectfully Submitted,



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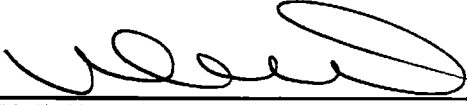
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**UNITED STATES DISTRICT COURT  
 CENTRAL DISTRICT OF CALIFORNIA  
 SOUTHERN DIVISION**

RETROPHIN, INC., a Delaware  
 Corporation,

Plaintiff,

vs.

QUESTCOR PHARMACEUTICALS,  
 INC., a California Corporation,

Defendant.

**COMPLAINT FOR:**

1. **RESTRAINT OF TRADE IN VIOLATION OF SECTION 1 OF THE SHERMAN ACT (15 U.S.C. § 1 ET SEQ.)**
2. **MONOPOLIZATION IN VIOLATION OF SECTION 2 OF THE SHERMAN ACT (15 U.S.C. § 2 ET SEQ.)**
3. **ATTEMPTED MONOPOLIZATION IN VIOLATION OF SECTION 2 OF THE SHERMAN ACT (15 U.S.C. § 2 ET SEQ.)**
4. **UNLAWFUL MERGER IN VIOLATION OF SECTION 7 OF THE CLAYTON ACT (15 U.S.C. § 18 ET SEQ.)**
5. **VIOLATION OF CALIFORNIA ANTITRUST LAWS**
6. **VIOLATION OF CALIFORNIA UNFAIR COMPETITION LAWS**

**DEMAND FOR JURY TRIAL**

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 SOUTHERN DIVISION

SA CV 14-00026-JLS (JPR)

Case# 2018-14059-103 Recorded at Montgomery County Prothonotary on 10/18/2019 1:07 PM, Fee = \$0.00. The filer certifies that this filing complies with the provisions of the Public Access Policy of the Unified Judicial System of Pennsylvania: Case Records of the Appellate and Trial Courts that require filing confidential information and documents differently than non-confidential information and documents.

JAN - 7 2014

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 CENTRAL DISTRICT OF CALIFORNIA  
 SOUTHERN DIVISION



1 Plaintiff Retrophin, Inc. ("Retrophin"), as and for its complaint against  
 2 Defendant Questcor Pharmaceuticals, Inc. ("Questcor"), alleges as follows:

3 **Nature of the Action**

4 1. Questcor is a monopolist. It is the sole provider in the US of approved  
 5 therapeutic preparations of adrenocorticotrophic hormone ("ACTH"), a drug used to  
 6 treat certain life threatening and often fatal diseases. Questcor's ACTH drug is sold  
 7 under the brand name H.P. Acthar Gel ("Acthar"). The drug is not patented.

8 2. Questcor acquired the rights to Acthar in 2001. At the time, Acthar sold  
 9 for \$50 a vial or less. Since then, Questcor has raised the price to \$28,000 – a  
 10 56,000% price increase.

11 3. Questcor is able to charge such an extortionate price for Acthar because it  
 12 holds a monopoly in the US. Its monopoly exists for several reasons. First, Acthar is  
 13 the only long acting ACTH therapeutic drug approved by the Food and Drug  
 14 Administration ("FDA") for use in the US. Second, Acthar is the most effective and  
 15 dominant first line treatment for Infantile Spasms, an often fatal disorder that causes  
 16 epileptic type seizures in babies, toddlers and children under the age of 5. In addition,  
 17 Questcor has obtained "Orphan Drug Designation" for Acthar from the FDA under the  
 18 Orphan Drug Act, 21 USC §§301 *et seq.*, giving it the exclusive right to market  
 19 Acthar – and its chemical equivalent – for use in treating Infantile Spasms. Third,  
 20 Acthar is also the most commonly used treatment of last resort for patients suffering  
 21 from Nephrotic Syndrome, a condition that results in excessive protein being secreted  
 22 through the urine that destroys the kidneys and can lead to kidney failure. Treatments  
 23 of last resort, as the term implies, are used for patients who do not respond to or  
 24 cannot tolerate other therapies used to treat their illness.

25 4. In June of 2013, plaintiff Retrophin was poised to challenge Questcor's  
 26 monopoly. It had negotiated an agreement to purchase from Novartis AG  
 27 ("Novartis"), the rights to sell in the US a product called Synacthen, an ACTH drug  
 28 that contains the same sequence of the first 24 amino acids that is found in Acthar.

1 While there are differences between Acthar and Synacthen – the two are not  
2 chemically identical beyond the first 24 amino acids and they are produced differently  
3 – Synacthen has been sold for years outside of the US for the treatment of Infantile  
4 Spasms, Nephrotic Syndrome, Multiple Sclerosis and other diseases. On information  
5 and belief, it is not currently sold in the US because it has never been submitted to the  
6 FDA for approval.

7 5. Retrophin planned to obtain FDA approval to sell Synacthen in the US  
8 and compete head to head against Questor by dramatically undercutting Questcor's  
9 price for Acthar. It had negotiated and was ready to sign an agreement to purchase the  
10 US rights to Synacthen from Novartis. The signing was scheduled for June 11, 2013.  
11 The signing of the agreement was so imminent that a press release had been prepared  
12 to announce the deal.

13 6. On June 11, 2013, the day Retrophin was to sign its agreement with  
14 Novartis, Questcor swept in and acquired the rights to Synacthen. In so doing, it  
15 preserved and entrenched its ACTH monopoly in the US and eliminated the  
16 competitive threat posed by Retrophin's acquisition of Synacthen. There was no  
17 procompetitive aspect of Questcor's acquisition of Synacthen.

18 7. When it acquired the rights to Acthar, Questcor did not make a  
19 Premerger Notification Filing with the Department of Justice and the Federal Trade  
20 Commission under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, 15  
21 USC, §18a *et seq.*

22 8. Questcor was quite aware, however, that its agreement with Novartis  
23 raised serious antitrust questions. The agreement provides that, if Questcor is forced  
24 to divest its rights to Synacthen on antitrust grounds, Novartis will keep the entire \$60  
25 million that Questcor had paid it. In addition, Questcor remains obligated to make all  
26 future milestone payments owed to Novartis under that agreement – an amount in  
27 excess of \$75 million. Questcor has accepted the entire economic risk – an amount in  
28

1 excess of \$135 million – that the agreement with Novartis would be deemed illegal  
2 under the antitrust laws.

3 9. Questcor's acquisition of Synacthen has delayed, and may completely  
4 foreclose, Retrophin's entry into the markets defined below. It will delay, and may  
5 completely prevent, Retrophin from competing against Questcor. Retrophin brings  
6 this lawsuit to recover the damages it has incurred as a result of Questcor's  
7 anticompetitive and monopolistic conduct. It also seeks injunctive relief against  
8 Questcor's continuation of such conduct.

### 9 The Parties

10 10. Plaintiff Retrophin is organized and exists under the laws of Delaware.  
11 Its principal place of business is located at 777 Third Avenue, 22nd Floor, New York,  
12 New York 10017. It also does business in California and Massachusetts.

13 11. Retrophin is a biopharmaceutical company focused on the development,  
14 acquisition and commercialization of drugs for the treatment of serious, catastrophic  
15 or rare diseases for which there are currently no viable options for patients. The  
16 diseases on which Retrophin focuses are often considered "orphan" diseases because  
17 they affect fewer than 200,000 patients in the United States. Retrophin has acquired  
18 and is building a pipeline of innovative product candidates for several catastrophic  
19 diseases, including: Focal Segmental Glomerulosclerosis, a kidney disease;  
20 Pantothenate Kinase-Associated Neurodegeneration; and Duchenne Muscular  
21 Dystrophy.

22 12. Defendant Questcor is a corporation organized and existing under the  
23 laws of the State of California. It maintains its principal place of business in  
24 Anaheim, California.

### 25 Jurisdiction and Venue

26 13. Retrophin brings this action under Sections 4 and 16 of the Clayton Act,  
27 15 U.S.C. §§15 and 26, to recover treble damages and costs of suit, including  
28 reasonable attorneys' fees, and for injunctive relief, for injuries suffered by Retrophin

1 alleged herein and arising from Questcor's continuing violations of Section 1 of the  
 2 Sherman Act, 15 U.S.C. § 1, Section 2 of the Sherman Act, 15 U.S.C. § 2, and Section  
 3 7 of the Clayton Act, 15 U.S.C. § 18. Jurisdiction for this action is invoked under  
 4 Sections 4 and 16 of the Clayton Act, as amended, 15 U.S.C. §§ 15 and 26, and 28  
 5 U.S.C. §§ 1331 and 1337(a).

6 14. Additionally, this Court has diversity jurisdiction over this action  
 7 pursuant to 28 U.S.C. § 1332(a) because the controversy exceeds the sum or value of  
 8 \$75,000 and Retrophin and Questcor are citizens of different states. This Court has  
 9 supplemental jurisdiction over Retrophin's state law claims pursuant to 28 U.S.C. §  
 10 1367(a).

11 15. Venue in this Court exists by virtue of Sections 4 and 12 of the Clayton  
 12 Act, as amended, 15 U.S.C. §§ 15 and 22, and 28 U.S.C. § 1391(c). Defendant  
 13 Questcor is found, has agents, transacts and is doing business in this District, and the  
 14 unlawful activities complained of herein were carried on, in substantial part, within  
 15 this District.

16 16. Defendant is subject to personal jurisdiction in this Court because it  
 17 resides in this District and transacts business in this District.

### 18 **Trade and Commerce**

19 17. The pharmaceutical products at issue in this case are sold in Interstate  
 20 Commerce, and the unlawful activities alleged in this Complaint have occurred in, and  
 21 have had and will have, a substantial effect upon, Interstate Commerce.

### 22 **The Relevant Markets**

23 18. There are a number of separate relevant product markets at issue in this  
 24 case. They include: (a) the market for ACTH therapeutic drugs (the "ACTH  
 25 Therapeutic Drug Market"); (b) the market for first-line drug treatments for Infantile  
 26 Spasms (the "Infantile Spasms Market"); and (c) the market for treatments of last  
 27 resort for Nephrotic Syndrome for those patients who do not respond to or cannot  
 28 tolerate primary and secondary treatments for that disease (the "Nephrotic Syndrome

1 Market”). The relevant geographic markets for each of these three relevant product  
2 markets is the United States, since drugs available in any of these markets are subject  
3 to FDA regulation. The ACTH Therapeutic Drug, Infantile Spasms, and Nephrotic  
4 Syndrome Markets are collectively referred to as the “Relevant Markets.”

5 **The ACTH Therapeutic Drug Market**

6 19. ACTH is a drug used to treat certain life threatening and often fatal  
7 diseases, including Infantile Spasms and Nephrotic Syndrome. It is a polypeptide  
8 tropic hormone produced and secreted by the anterior pituitary gland. In the human  
9 body, ACTH activates the Melanocortin System and is referred to as a “Melanocortin  
10 agonist.” The Melanocortin System affects a wide array of bodily functions ranging  
11 from skin pigmentation, inflammation, energy homeostasis and sexual function. As a  
12 consequence, ACTH can be used as a therapy for a variety of illnesses resulting from  
13 improper functioning of the Melanocortin System, including Infantile Spasms and  
14 Nephrotic Syndrome. There is no reasonable interchangeability between drug  
15 therapies used to treat other diseases and ACTH drug therapies used to stimulate the  
16 Melanocortin System.

17 20. Acthar is an ACTH. It is the only FDA approved long-acting ACTH  
18 available in the US. It is also the only FDA approved long-acting melanocortin  
19 agonist available in the US.

20 21. ACTH products have been approved for use as diagnostic agents which  
21 are used to test for the presence of certain conditions or diseases. However, those  
22 products are short acting and are not used as therapies in treating illnesses.

23 22. Consumers faced with a small but significant non-transitory increase in  
24 the price of ACTH therapeutic drugs, cannot and will not shift to other classes of  
25 drugs such that the increase in price will be rendered unprofitable. This is evidenced  
26 by the fact that Questcor, the only supplier of ACTH for therapeutic purposes in the  
27 US, has raised the price of a vial of Acthar to \$28,000 and is able to maintain that  
28 price.



1 23. FDA regulation and the difficulty of developing and manufacturing  
2 ACTH based therapeutic drugs reduce or eliminate any “supply elasticity” whereby  
3 manufacturers of other drug therapies convert their existing manufacturing facilities to  
4 the manufacture of ACTH therapeutic drugs.

5 24. The relevant geographic market for ACTH therapeutic drugs is national  
6 because therapeutic ACTH drugs cannot be sold in the US without FDA approval.

7 **The Infantile Spasms Market**

8 25. Babies and little children suffering from Infantile Spasms must have  
9 treatments that cure that affliction. Without it they suffer from epileptic type seizures  
10 and other symptoms of the disease. If untreated, they may suffer permanent brain or  
11 neurological damage and may develop other seizure disorders. The disease can be  
12 fatal. Only therapies that treat Infantile Spasm Syndrome can meet the medical needs  
13 of these patients. Therapies for other diseases do not cure or control Infantile Spasms  
14 and are not substitutes for Infantile Spasm therapeutics. There is no reasonable  
15 interchangeability between drug therapies used to treat other diseases and drug  
16 therapies used to treat children with Infantile Spasms.

17 26. Consumers faced with a small but significant non-transitory increase in  
18 the price of therapeutic drugs to treat Infantile Spasms, cannot and will not shift to  
19 other drug treatments for Infantile Spasms such that the increase in price will be  
20 rendered unprofitable. This is evidenced by the fact that Questcor has raised the price  
21 of a vial of Acthar to \$28,000 and is able to maintain that price.

22 27. There are also regulatory entry barriers that limit the Relevant Market to  
23 first line therapies for Infantile Spasms. In 2010, Questcor obtained from the FDA,  
24 “Orphan Drug designation” for Acthar for Infantile Spasms under the Orphan Drug  
25 Act. Despite the fact that Acthar is not patented, the Orphan Drug designation gives  
26 Questcor a seven year exclusive right to sell Acthar, and its chemical equivalent, for  
27 Infantile Spasms with immunity from generic competition. Questcor’s exclusive  
28 marketing right extends to 2017. Therapies that are excluded by Acthar’s Orphans

1 Drug Designation (generic versions of Acthar) cannot be labeled or marketed for the  
2 treatment of Infantile Spasms.

3 28. FDA regulation and the difficulty of developing and manufacturing  
4 treatments for Infantile Spasms preclude any "supply elasticity" whereby  
5 manufacturers of other drug therapies convert their manufacturing facilities to the  
6 manufacture of Infantile Spasm therapies.

7 29. The relevant geographic market for first line Infantile Spasm drug  
8 therapies is national because therapeutic drugs cannot be marketed in the US for  
9 Infantile Spasms without FDA approval.

### 10 **The Nephrotic Syndrome Market**

11 30. Nephrotic Syndrome is a condition in which excessive amounts of  
12 protein pass through the kidneys and are secreted through the urine. This results in  
13 kidney damage and can lead to kidney failure. Nephrotic Syndrome is treated on a  
14 first and second line basis with corticosteroids, such as Prednisone, or  
15 immunosuppressant drugs. In some patients the disease does not respond to these  
16 treatments and in others the patient cannot tolerate the drugs' side effects. In such  
17 cases, ACTH (Acthar) is the primary and dominant treatment of last resort. Only  
18 therapies that treat Nephrotic Syndrome effectively can meet the medical needs of  
19 Nephrotic Syndrome patients who do not respond to or cannot tolerate traditional first  
20 and second line therapies for that illness. Therapies for other diseases do not cure or  
21 control Nephrotic Syndrome and are not substitutes for last resort treatments for  
22 Nephrotic Syndrome. There is no reasonable interchangeability between drug  
23 therapies used to treat other diseases and drug therapies used to treat victims of  
24 Nephrotic Syndrome.

25 31. Consumers faced with a small but significant non-transitory increase in  
26 the price of last resort therapeutic drugs to treat Nephrotic Syndrome cannot and will  
27 not shift to other drug treatments such that the increase in price will be rendered  
28

1 unprofitable. This is evidenced by the fact that Questcor has raised the price of a vial  
2 of Acthar to \$28,000 and is able to maintain that price.

3 32. There are also regulatory entry barriers that limit the Relevant Market to  
4 therapies of last resort for Nephrotic Syndrome. Therapies for other conditions cannot  
5 be marketed for the treatment of Nephrotic Syndrome without FDA approval. In  
6 addition, it is particularly difficult for the maker of a generic drug to obtain FDA  
7 approval when it is trying to prove that its synthetically manufactured product, which  
8 is manufactured in a laboratory setting, is the biopharmaceutical equivalent of a drug  
9 such as Acthar which is produced from animals.

10 33. FDA regulation and the difficulty of developing and manufacturing  
11 treatments for Nephrotic Syndrome preclude any "supply elasticity" whereby  
12 manufacturers of other drug therapies convert their manufacturing facilities to the  
13 manufacture of Nephrotic Syndrome therapies.

14 34. The relevant geographic market for therapies of last resort for Nephrotic  
15 Syndrome is national because such therapies cannot be marketed in the US for  
16 Nephrotic Syndrome without FDA approval.

### 17 **Questcor Has Market and Monopoly Power in the Relevant Markets**

18 35. There are no meaningful substitutes for Acthar or ACTH in the Relevant  
19 Markets. Nor are manufacturers of other pharmaceutical products able to shift their  
20 production to the manufacture of Acthar or other ACTH products. Even if they were  
21 able to do so, they could not sell those products without first obtaining FDA approval.  
22 Questcor has market and monopoly power in all of the Relevant Markets.

23 36. Questcor's monopoly power in all three of the Relevant Markets is  
24 further evidenced by a single price increase that it imposed in 2007. In that year,  
25 Questcor raised the price of Acthar from \$1,650 per vial to \$23,000 per vial, an  
26 overnight increase of over 1,300%. Questcor's ability to make that price increase  
27 "stick" is conclusive evidence of its market and monopoly power.  
28



### **The ACTH Therapeutic Drug Market**

37. In the ACTH Therapeutic Drug Market, Acthar is the only FDA approved long acting ACTH therapeutic drug available to consumers in the United States.

38. Questcor's market and monopoly power in the ACTH Therapeutic Drug Market is further protected by the fact that other chemical variations of ACTH for use as therapeutic drugs require FDA approval for sale in the United States.

39. Questcor effectively has 100% of the market for ACTH Therapeutic Drugs. It has market and monopoly power in that market which is dramatically demonstrated by its continued ability to charge \$28,000 for a vial of Acthar.

### **The Infantile Spasms Market**

40. In the Infantile Spasms Market, Acthar is considered the "gold standard" of treatment.

41. Questcor's market and monopoly power in the Infantile Spasms Market is protected by the Orphan Drug Designation that protects Questcor from generic competition to Acthar. Its monopoly position is further protected by the fact that alternative therapies, that would not be precluded by the Orphan Designation, require FDA approval if they are to be marketed as therapies for Infantile Spasms.

42. Questcor admits that it has more than 50% share of the Infantile Spasms Market and its actual market share may be far greater. Questcor's market and monopoly power in the Infantile Spasms Market is demonstrated dramatically by its continued ability to charge \$28,000 for a vial of Acthar.

### **The Nephrotic Syndrome Market**

43. In the Nephrotic Syndrome Market, Acthar is the primary and dominant treatment of last resort for Nephrotic Syndrome patients who do not respond to or cannot tolerate first or second line treatments for that disease.

1 44. Questcor's market and monopoly power in the Nephrotic Syndrome  
2 Market is further protected by the fact that alternative drug therapies require FDA  
3 approval if they are to be marketed as therapies for Nephrotic Syndrome.

4 45. Questcor's market and monopoly power in the Nephrotic Syndrome  
5 Market is demonstrated dramatically by its continued ability to charge \$28,000 for a  
6 vial of Acthar.

7 **Retrophin's Acquisition of Synacthen Threatened Questcor's Monopoly**

8 46. Synacthen is an ACTH derivative that has been sold for years outside of  
9 the US and has been used successfully to treat patients with Infantile Spasms and  
10 Nephrotic Syndrome in other countries. It has not been commercially developed in  
11 the US and it has not been submitted to the FDA for approval for therapeutic use.

12 47. Synacthen is similar, but not chemically identical, to Acthar. Both drugs  
13 share the identical sequence of the first 24 amino acids in their respective molecules.  
14 This sequence of amino acids gives both drugs their therapeutic properties. Acthar,  
15 however, has a longer amino acid chain. The two drugs are also produced in very  
16 different ways. Acthar is "porcine derived." It is extracted from the pituitary gland  
17 found in the brains of slaughtered pigs. Synacthen, by contrast, is synthetically  
18 manufactured in a laboratory setting. These differences give Synacthen three  
19 competitive advantages over Acthar. First, Synacthen is less expensive to  
20 manufacture. Second, because it is manufactured in a controlled setting, the product is  
21 less susceptible to variation. Third, consumers are more comfortable knowing that the  
22 drugs they are taking – or giving to their infants – are produced in a sterile  
23 environment rather than being derived from slaughtered animals.

24 48. Retrophin planned to purchase the rights to Synacthen, obtain FDA  
25 approval for its use as a therapeutic, and enter the Relevant Markets in competition  
26 with Questcor. Retrophin planned to price Synacthen at a fraction of the price  
27 charged by Questcor and use its competitive pricing and Synacthen's other  
28 competitive advantages to take substantial market share from Acthar.

1           49. In the late summer of 2012, Retrophin entered negotiations with Novartis  
2 to purchase the rights to manufacture and sell Synacthen in the US. After  
3 approximately nine months of due diligence and negotiations, Retrophin and Novartis  
4 agreed to terms on which Retrophin would acquire the rights to Synacthen. Final  
5 documents had been prepared and were merely awaiting the parties' signatures. The  
6 signing was set for June 11, 2013. Retrophin had prepared a press release announcing  
7 the deal.

8           50. In anticipation of the transaction, Retrophin had prepared a plan to obtain  
9 regulatory approvals for, and sell Synacthen. It devised a strategy for going directly to  
10 Phase III clinical drug trials in order to obtain FDA approval for the use of Synacthen  
11 to treat Infantile Spasms and Nephrotic Syndrome. It also planned to file a Treatment  
12 Investigational New Drug Application which, if approved by the FDA, would have  
13 allowed Retrophin to offer Synacthen to patients for free while it was awaiting FDA  
14 approval to market Synacthen for Infantile Spasms and Nephrotic Syndrome. This  
15 would have given patients immediate relief from Questcor's pricing and would have  
16 developed substantial goodwill for Retrophin and Synacthen in both the patient and  
17 medical communities. Retrophin believed that the history of Synacthen's use in other  
18 countries would aid it in obtaining FDA approval.

19           51. In anticipation of the product launch, Retrophin had put in place a  
20 clinical apparatus to conduct clinical trials necessary to obtain FDA approval. It  
21 planned to begin to market Synacthen upon FDA approval.

22           52. Given its expertise as a biopharmaceutical company focusing on rare  
23 diseases, Retrophin was ready, willing and able to enter the Relevant Markets with  
24 Synacthen subject to FDA approval. Retrophin's entry into the Relevant Markets  
25 would have broken Questcor's monopoly. The result would have been  
26 unambiguously procompetitive. Retrophin's entry into the market and its introduction  
27 of Synacthen as an alternative to Acthar would have benefitted all participants in the  
28 markets – other than Questcor. Prices to patients and payors would have dropped;

1 patients who were unable to pay for the drug would have been able to get it; other  
 2 patients who were forced by Questcor's pricing to limit their dosages of the drug  
 3 would have been able to take the medically prescribed amounts; and Retrophin would  
 4 have earned substantial profits from sales of its product.

### 5 **Questcor Illegally Acquires Synacthen to Preserve its Monopoly**

6 53. Faced with a direct threat to its monopoly, Questcor acted to preserve its  
 7 market dominance and its ability to charge extraordinary prices for Acthar. It swept in  
 8 and secretly negotiated a deal to buy the rights to Synacthen from Novartis.

9 54. On June 11, 2013, the very day that Retrophin and Novartis were to sign  
 10 their agreement, Questcor acquired the rights to Synacthen. The acquisition was  
 11 closed on the day of the announcement. Questcor made no Premerger Notification  
 12 filing with the Department of Justice and the Federal Trade Commission under the  
 13 Hart Scott Rodino Act Antitrust Improvements Act of 1976. Nor did it observe the  
 14 waiting period provided by the Hart Scott Act before closing the acquisition.

15 55. As part of the Agreement, the entire risk of an antitrust challenge to the  
 16 transaction is borne by Questcor. The Agreement between Novartis and Questcor  
 17 provides that Novartis receives the full consideration it is entitled to from Questcor  
 18 even if the US antitrust enforcement agencies (The Federal Trade Commission or the  
 19 Department of Justice) force Questcor to divest its rights in Synacthen. If such a  
 20 divestiture occurs, the Agreement provides that Novartis keeps the entire \$60 million  
 21 that Questcor has paid it and Questcor will make all future milestone payments  
 22 required by the Agreement – an amount in excess of \$75 million. In short, the  
 23 acquisition of the rights to Synacthen was so important to Questcor that it put at least  
 24 \$135 million at risk to keep Synacthen out of Retrophin's hands. There was no  
 25 procompetitive aspect of Questcor's acquisition of Synacthen.

26 56. Questcor's acquisition of the rights to Synacthen unreasonably restrained  
 27 trade, maintained Questcor's monopolies and may result in a substantial lessening of  
 28 competition in the Relevant Markets. As a result of Questcor's acquisition of the

1 rights to Synacthen, prices to patients and payors for Acthar will remain at monopoly  
2 levels; patients who are unable to pay for the drug will not be able to get it;  
3 other patients who are forced by Questcor's pricing to limit their dosages of the drug  
4 will not be able to take the medically prescribed amounts; and Retrophin will not earn  
5 the substantial profits it expected to earn from selling Synacthen at a fraction of the  
6 price Questcor charges for Acthar.

7 **Retrophin Is Continuing to Try to Enter the Relevant Markets**

8 57. Despite Questcor's anticompetitive and monopolistic conduct, Retrophin  
9 is continuing to try to enter the Relevant Product Markets. To that end, it has taken  
10 the highly unusual step of trying to create from scratch a drug – that it has designated  
11 as RE-034 – that will match Synacthen. Retrophin is endeavoring to create a new  
12 formulation of the drug that will incorporate the same active pharmaceutical  
13 ingredient used in Synacthen and match Synacthen's therapeutic effects for patients  
14 suffering from Infantile Spasms and Nephrotic Syndrome.

15 58. Retrophin's efforts to develop RE-034 will take substantial time and  
16 money and will require FDA approval. It will also require that the drug successfully  
17 complete both Phase I and Phase III clinical trials for both Infantile Spasms and  
18 Nephrotic Syndrome. There is no guarantee that RE-034 will succeed in the clinical  
19 trials or that Retrophin will succeed in obtaining FDA approval or entering the  
20 Relevant Markets.

21 59. Entering the Relevant Markets through RE-034 is more difficult, risky  
22 and time consuming than entering those markets through Synacthen. Synacthen is an  
23 existing product that has been manufactured and used outside of the US for decades in  
24 the treatment of a variety of illnesses, including Infantile Spasms and Nephrotic  
25 Syndrome. The owner of the rights to Synacthen has the information, know-how and  
26 ability to manufacture the drug and has decades of clinical data from outside the  
27 United States that can be used to facilitate and speed the regulatory approval process  
28



1 in the US. Retrophin will need to develop all of that knowledge from scratch in  
2 seeking to enter the Relevant Markets with RE-034.

3 60. Entering the Relevant Markets through RE-034 will be more difficult,  
4 less likely to succeed and take longer than entry into those markets through the  
5 acquisition of Synacthen. Questcor's conduct has delayed, and may entirely foreclose,  
6 Retrophin from entering the Relevant Markets.

7 **Questcor Has Damaged Competition in the Relevant Markets and Has Caused**  
8 **Retrophin to Suffer Both Injury in Fact and Antitrust Injury**

9 61. Questcor's unlawful acquisition of the rights to Synacthen has foreclosed  
10 or delayed Retrophin from entering the Relevant Markets, has restrained trade, and  
11 has preserved and entrenched Questcor's monopoly and may substantially lessen  
12 competition. As a result, competition in the Relevant Markets has been damaged and  
13 Retrophin has been injured. Those injuries are intertwined and inseparable.  
14 Excluding or delaying Retrophin from entering the Relevant Markets with Synacthen  
15 was and is an integral aspect of Questcor's anticompetitive conduct.

16 62. Retrophin has suffered and continues to suffer injury in fact from  
17 Questcor's acquisition of the rights to Synacthen and the preservation of its monopoly.

18 63. Retrophin has suffered and continues to suffer antitrust injury from  
19 Questcor's acquisition of the rights to Synacthen and the preservation of its monopoly.  
20 Retrophin has been injured directly as a result of Questcor's unlawful conduct.  
21 Retrophin is a potential entrant into the Relevant Markets and, but for Questcor's  
22 unlawful conduct, would be entering those markets with Synacthen. There are no  
23 aspects of Questcor's conduct that are beneficial to competition. Retrophin's injury is  
24 an integral aspect of Questcor's unlawful conduct; flows from that which renders  
25 Questcor's conduct unlawful; and its injury is of the type the antitrust laws were  
26 intended to prevent.  
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**FIRST CAUSE OF ACTION**  
**(COMBINATION IN THE RESTRAINT OF TRADE IN VIOLATION OF**  
**SECTION 1 OF THE SHERMAN ACT)**

64. Retrophin repeats and realleges the allegations set forth in paragraphs 1 through 63 as if fully set forth herein.

65. In acquiring the rights to Synacthen, Questcor entered into a contract, conspiracy or combination that unreasonably restrains trade in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1.

66. Questcor's acquisition of the rights to Synacthen unlawfully and unreasonably restrains trade by preventing or delaying Retrophin from entering the Relevant Markets and challenging Questcor's market power in those markets.

67. Questcor's violation of Section 1 of the Sherman Act has caused, and will cause, damages to Retrophin in an amount to be determined at trial, such damages to be trebled in accordance with Section 4 of the Clayton Act, 15 U.S.C. § 15.

68. Questcor's unlawful conduct is ongoing, irreparably injures Retrophin, harms the public interest, and unless restrained will continue. Retrophin has no adequate remedy at law.

**SECOND CAUSE OF ACTION**  
**(MONOPOLIZATION IN VIOLATION OF SECTION 2 OF THE SHERMAN**  
**ACT)**

69. Retrophin repeats and realleges the allegations set forth in paragraphs 1 through 68 as if fully set forth herein.

70. Questcor has monopoly power in the Relevant Markets. In acquiring the rights to Synacthen in the US, Questcor has intentionally acted to maintain and entrench its monopoly position in Relevant Markets, and has done so, in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

72. Questcor's unlawful conduct is ongoing, irreparably injures Retrophin, harms the public interest, and unless restrained will continue. Retrophin has no adequate remedy at law.

**(ATTEMPTED MONOPOLIZATION IN VIOLATION OF SECTION 2 OF  
THE SHERMAN ACT)**

74. In acquiring the rights to Synacthen, Questcor has engaged in monopolistic and anticompetitive conduct with the specific purpose and intent of monopolizing the Relevant Markets in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

76. A dangerous probability exists that Questcor has succeeded, and if not restrained, will continue to succeed in monopolizing the Relevant Markets.

77. Questcor's acts of attempted monopolization has unlawfully prevented and delayed Retrophin from entering the Relevant Markets and otherwise injure competition in those markets by reducing choice, inflating prices, and lessening innovation.

78. Questcor's violation of Section 2 of the Sherman Act has caused, and will cause, damages to Retrophin in an amount to be determined at trial, such damages to be trebled in accordance with Section 4 of the Clayton Act, 15 U.S.C. § 15.



79. Questcor's unlawful conduct is ongoing, irreparably injures Retrophin, harms the public interest, and unless restrained will continue. Retrophin has no adequate remedy at law.

#### **FOURTH CAUSE OF ACTION**

#### **(UNLAWFUL MERGER IN VIOLATION OF SECTION 7 OF THE CLAYTON ACT)**

80. Retrophin repeats and realleges the allegations set forth in paragraphs 1 through 79 as if fully set forth herein.

81. Questcor's acquisition of the rights to Synacthen is likely to substantially lessen competition in interstate trade and commerce in violation of Section 7 of the Clayton Act, 15 U.S.C. § 18.

82. Questcor's acquisition of the rights to Synacthen is likely to result in a substantial lessening of competition in the Relevant Markets.

83. Questcor's violation of Section 7 of the Clayton Act has caused, and will cause, damages to Retrophin in an amount to be determined at trial, such damages to be trebled in accordance with Section 4 of the Clayton Act, 15 U.S.C. § 15.

84. Questcor's unlawful conduct is ongoing, irreparably injures Retrophin, harms the public interest, and unless restrained will continue. Retrophin has no adequate remedy at law.

#### **FIFTH CAUSE OF ACTION**

#### **(VIOLATION OF CALIFORNIA ANTITRUST LAWS)**

85. Retrophin repeats and realleges the allegations set forth in paragraphs 1 through 84 as if fully set forth herein.

86. In acquiring the rights to Synacthen, Questcor entered into and engaged in a continuing unlawful trust in restraint of the trade and commerce described above in violation of the California antitrust laws referenced below. Questcor has acted in violation of these laws in an effort to maintain, entrench, and/or create a monopoly,

1 and otherwise injure competition in the Relevant Markets. Questcor's conduct  
2 substantially affected commerce in California.

3 87. In acquiring the rights to Synacthen in the US, Questcor has maintained  
4 and entrenched its monopoly position in the Relevant Markets.

5 88. Questcor's acquisition of the rights to Synacthen is likely to result in a  
6 substantial lessening of competition in the Relevant Markets.

7 89. By reason of the foregoing, Questcor violated California's Cartwright  
8 Act, California Business and Professions Code §§ 16720 *et seq.*

9 90. Questcor's violation of California's Cartwright Act, California Business  
10 and Professions Code §§ 16720 *et seq.* has caused, and will cause, damages to  
11 Retrophin in an amount to be determined at trial, with such damages to be trebled.

12 91. Questcor's unlawful conduct is ongoing, irreparably injures Retrophin,  
13 harms the public interest, and unless restrained will continue. Retrophin has no  
14 adequate remedy at law.

### 15 **SIXTH CAUSE OF ACTION**

#### 16 **(UNFAIR COMPETITION UNDER CAL. BUS. & PROF. CODE**

#### 17 **§ 17200 *ET SEQ.*)**

18 92. Retrophin repeats and realleges the allegations set forth in paragraphs 1  
19 through 91 as if fully set forth herein.

20 93. California Unfair Competition Law, Business and Professions Code  
21 Section 17200 *et seq.*, provides that "unfair competition shall mean and include any  
22 unlawful, unfair or fraudulent business act."

23 94. Questcor's conduct as alleged herein meets the "unlawfulness" prong of  
24 California Business and Professions Code §§ 17200 *et seq.* Questcor has committed  
25 and continues to commit unlawful business practices by illegally acquiring the rights  
26 to Synacthen and engaging in anticompetitive and monopolistic conduct in violation  
27 of antitrust laws.  
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19

1 D. DECLARING that Questcor's acquisition of the rights to Synacthen  
 2 constitutes an acquisition that may result in a substantial lessening of competition in  
 3 the Relevant Markets in violation of Section 7 of the Clayton Act;

4 E. DECLARING that Questcor's acquisition of the rights to Synacthen  
 5 constitutes an unlawful trust in restraint of trade and commerce in violation of  
 6 California Business and Professions Code §§ 16720 *et seq.*;

7 F. DECLARING that Questcor's acquisition of the rights to Synacthen  
 8 constitutes unfair competition in violation of California Business and Professions  
 9 Code § 17200 *et seq.*;

10 G. PERMANENTLY ENJOINING Questcor from enforcing or maintaining  
 11 its Rights to Synacthen under its agreement with Novartis or any similar formal or  
 12 informal agreement;

13 H. PERMANENTLY ENJOINING Questcor from engaging in further  
 14 anticompetitive conduct in violation of Section 1 of the Sherman Act;

15 I. PERMANENTLY ENJOINING Questcor from engaging in further  
 16 anticompetitive conduct in violation of Section 2 of the Sherman Act;

17 J. PERMANENTLY ENJOINING Questcor from engaging in further  
 18 anticompetitive conduct in violation of Section 7 of the Clayton Act;

19 K. PERMANENTLY ENJOINING Questcor from engaging in further  
 20 anticompetitive conduct in violation of California Business and Professions Code §§  
 21 16720, *et seq.*;

22 L. PERMANENTLY ENJOINING Questcor from engaging in further  
 23 unlawful and/or unfair business practices in violation of California Business and  
 24 Professions Code § 17200 *et seq.*;

25 M. DISGORGING any profits generated by Questcor as a result of its  
 26 unlawful and/or unfair business practices to the extent it constitutes restitution to  
 27 Retrophin;  
 28

1 N. AWARDING Retrophin damages in an amount to be proved at trial, such  
2 damages to be trebled, including its costs and attorneys' fees, pursuant to Section 4 of  
3 the Clayton Act, 15 U.S.C. § 15 and/or California's Cartwright Act, California  
4 Business and Professions Code §§ 16720, *et seq.*;

5 O. AWARDING Retrophin its costs, expenses and attorneys' fees incurred  
6 in connection with the action;

7 P. AWARDING Retrophin interest to the maximum extent permitted by  
8 law; and

9 Q. GRANTING Retrophin such other and further relief as this Court deems  
10 just and proper.

11 Dated: January 7, 2014

KATTEN MUCHIN ROSENMAN LLP

12  
13 By: 

14 Kristin L. Holland  
15 Attorneys for Plaintiff Retrophin, Inc.  
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**DEMAND FOR JURY TRIAL**

Retrophin hereby demands a trial by jury on all of its claims and causes of action.

Dated: January 7, 2014

KATTEN MUCHIN ROSENMAN LLP

By: 

Kristin L. Holland  
Attorneys for Plaintiff Retrophin, Inc.



**UNITED STATES DISTRICT COURT, CENTRAL DISTRICT OF CALIFORNIA  
CIVIL COVER SHEET**

<b>I. (a) PLAINTIFFS</b> ( Check box if you are representing yourself <input type="checkbox"/> )  Retrophin, Inc.	<b>DEFENDANTS</b> ( Check box if you are representing yourself <input type="checkbox"/> )  Questcor Pharmaceuticals, Inc.
<b>(b) County of Residence of First Listed Plaintiff</b> <u>New York, NY</u> <small>(EXCEPT IN U.S. PLAINTIFF CASES)</small>	<b>County of Residence of First Listed Defendant</b> <u>Orange, CA</u> <small>(IN U.S. PLAINTIFF CASES ONLY)</small>
<b>(c) Attorneys (Firm Name, Address and Telephone Number)</b> If you are representing yourself, provide the same information. Katten Muchin Rosenman LLP 2029 Century Park East, Suite 2600 Los Angeles, CA 90067-3012 310-788-4400	<b>Attorneys (Firm Name, Address and Telephone Number)</b> If you are representing yourself, provide the same information.  N/A

**II. BASIS OF JURISDICTION** (Place an X in one box only.)

- ☐ 1. U.S. Government Plaintiff
☒ 3. Federal Question (U.S. Government Not a Party)
☐ 2. U.S. Government Defendant
☐ 4. Diversity (Indicate Citizenship of Parties in Item III)

**III. CITIZENSHIP OF PRINCIPAL PARTIES**—For Diversity Cases Only  
(Place an X in one box for plaintiff and one for defendant)

- |   |                                |                                |   |   |   |
|---|--------------------------------|--------------------------------|---|---|---|
| Citizen of This State                   | PTF <input type="checkbox"/> 1 | DEF <input type="checkbox"/> 1 | Incorporated or Principal Place of Business in this State     | PTF <input type="checkbox"/> 4            | DEF <input checked="" type="checkbox"/> 4 |
| Citizen of Another State                | PTF <input type="checkbox"/> 2 | DEF <input type="checkbox"/> 2 | Incorporated and Principal Place of Business in Another State | PTF <input checked="" type="checkbox"/> 5 | DEF <input type="checkbox"/> 5            |
| Citizen or Subject of a Foreign Country | PTF <input type="checkbox"/> 3 | DEF <input type="checkbox"/> 3 | Foreign Nation  | PTF <input type="checkbox"/> 6            | DEF <input type="checkbox"/> 6            |

**IV. ORIGIN** (Place an X in one box only.)

- ☒ 1. Original Proceeding
☐ 2. Removed from State Court
☐ 3. Remanded from Appellate Court
☐ 4. Reinstated or Reopened
☐ 5. Transferred from Another District (Specify)
☐ 6. Multi-District Litigation

**V. REQUESTED IN COMPLAINT: JURY DEMAND:** ☒ Yes ☐ No (Check "Yes" only if demanded in complaint.)

**CLASS ACTION** under F.R.Cv.P. 23: ☐ Yes ☒ No **MONEY DEMANDED IN COMPLAINT:** \$ Over \$75k, TBD

**VI. CAUSE OF ACTION** (Cite the U.S. Civil Statute under which you are filing and write a brief statement of cause. Do not cite jurisdictional statutes unless diversity.)

Plaintiff is suing defendant for entering an illegal agreement and engaging in conduct that violates federal and state antitrust and competition laws, 15 U.S.C. §§ 1, 2, 18, and California Business and Professions Code §§ 16720, et seq, California Business and Professions Code §§ 17200, et seq

**VII. NATURE OF SUIT** (Place an X in one box only.)

OTHER STATUTES	CONTRACT	REAL PROPERTY CONT.	IMMIGRATION	PRISONER PETITIONS	PROPERTY RIGHTS
<input type="checkbox"/> 375 False Claims Act	<input type="checkbox"/> 110 Insurance	<input type="checkbox"/> 240 Torts to Land	<input type="checkbox"/> 462 Naturalization Application	<b>Habeas Corpus:</b>	<input type="checkbox"/> 820 Copyrights
<input type="checkbox"/> 400 State Reapportionment	<input type="checkbox"/> 120 Marine	<input type="checkbox"/> 245 Tort Product Liability	<input type="checkbox"/> 465 Other Immigration Actions	<input type="checkbox"/> 463 Alien Detainee	<input type="checkbox"/> 830 Patent
<input checked="" type="checkbox"/> 410 Antitrust	<input type="checkbox"/> 130 Miller Act	<input type="checkbox"/> 290 All Other Real Property	<b>TORTS</b>	<input type="checkbox"/> 510 Motions to Vacate Sentence	<input type="checkbox"/> 840 Trademark
<input type="checkbox"/> 430 Banks and Banking	<input type="checkbox"/> 140 Negotiable Instrument	<b>PERSONAL INJURY</b>	<b>PERSONAL PROPERTY</b>	<input type="checkbox"/> 530 General	<b>SOCIAL SECURITY</b>
<input type="checkbox"/> 450 Commerce/ICC Rates/Etc.	<input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment	<input type="checkbox"/> 310 Airplane	<input type="checkbox"/> 370 Other Fraud	<input type="checkbox"/> 535 Death Penalty	<input type="checkbox"/> 861 HIA (1395ff)
<input type="checkbox"/> 460 Deportation	<input type="checkbox"/> 151 Medicare Act	<input type="checkbox"/> 315 Airplane Product Liability	<input type="checkbox"/> 371 Truth in Lending	<b>Other:</b>	<input type="checkbox"/> 862 Black Lung (923)
<input type="checkbox"/> 470 Racketeer Influenced & Corrupt Org.	<input type="checkbox"/> 152 Recovery of Defaulted Student Loan (Excl. Vet.)	<input type="checkbox"/> 320 Assault, Libel & Slander	<input type="checkbox"/> 380 Other Personal Property Damage	<input type="checkbox"/> 540 Mandamus/Other	<input type="checkbox"/> 863 DIWC/DIWW (405 (g))
<input type="checkbox"/> 480 Consumer Credit	<input type="checkbox"/> 153 Recovery of Overpayment of Vet. Benefits	<input type="checkbox"/> 330 Fed. Employers' Liability	<input type="checkbox"/> 385 Property Damage Product Liability	<input type="checkbox"/> 550 Civil Rights	<input type="checkbox"/> 864 SSID Title XVI
<input type="checkbox"/> 490 Cable/Sat TV	<input type="checkbox"/> 160 Stockholders' Suits	<input type="checkbox"/> 340 Marine	<b>BANKRUPTCY</b>	<input type="checkbox"/> 555 Prison Condition	<input type="checkbox"/> 865 RSI (405 (g))
<input type="checkbox"/> 850 Securities/Commodities/Exchange	<input type="checkbox"/> 190 Other Contract	<input type="checkbox"/> 345 Marine Product Liability	<input type="checkbox"/> 422 Appeal 28 USC 158	<input type="checkbox"/> 560 Civil Detainee Conditions of Confinement	<b>FEDERAL TAX SUITS</b>
<input type="checkbox"/> 890 Other Statutory Actions	<input type="checkbox"/> 195 Contract Product Liability	<input type="checkbox"/> 350 Motor Vehicle	<input type="checkbox"/> 423 Withdrawal 28 USC 157	<b>FORFEITURE/PENALTY</b>	<input type="checkbox"/> 870 Taxes (U.S. Plaintiff or Defendant)
<input type="checkbox"/> 891 Agricultural Acts	<input type="checkbox"/> 196 Franchise	<input type="checkbox"/> 355 Motor Vehicle Product Liability	<b>CIVIL RIGHTS</b>	<input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC 881	<input type="checkbox"/> 871 IRS-Third Party 26 USC 7609
<input type="checkbox"/> 893 Environmental Matters	<b>REAL PROPERTY</b>	<input type="checkbox"/> 360 Other Personal Injury	<input type="checkbox"/> 440 Other Civil Rights	<input type="checkbox"/> 690 Other	
<input type="checkbox"/> 895 Freedom of Info. Act	<input type="checkbox"/> 210 Land Condemnation	<input type="checkbox"/> 362 Personal Injury-Med Malpractice	<input type="checkbox"/> 441 Voting	<b>LABOR</b>	
<input type="checkbox"/> 896 Arbitration	<input type="checkbox"/> 220 Foreclosure	<input type="checkbox"/> 365 Personal Injury-Product Liability	<input type="checkbox"/> 442 Employment	<input type="checkbox"/> 710 Fair Labor Standards Act	
<input type="checkbox"/> 899 Admin. Procedures Act/Review of Appeal of Agency Decision	<input type="checkbox"/> 230 Rent Lease & Ejectment	<input type="checkbox"/> 367 Health Care/Pharmaceutical Personal Injury Product Liability	<input type="checkbox"/> 443 Housing/Accommodations	<input type="checkbox"/> 720 Labor/Mgmt. Relations	
<input type="checkbox"/> 950 Constitutionality of State Statutes		<input type="checkbox"/> 368 Asbestos Personal Injury Product Liability	<input type="checkbox"/> 445 American with Disabilities-Employment	<input type="checkbox"/> 740 Railway Labor Act	
			<input type="checkbox"/> 446 American with Disabilities-Other	<input type="checkbox"/> 751 Family and Medical Leave Act	
			<input type="checkbox"/> 448 Education	<input type="checkbox"/> 790 Other Labor Litigation	
				<input type="checkbox"/> 791 Employee Ret. Inc. Security Act	

FOR OFFICE USE ONLY:

Case Number:

CV-71 (11/13)

CIVIL COVER SHEET

Page 1 of 3

**UNITED STATES DISTRICT COURT, CENTRAL DISTRICT OF CALIFORNIA  
CIVIL COVER SHEET**

**VIII. VENUE:** Your answers to the questions below will determine the division of the Court to which this case will most likely be initially assigned. This initial assignment is subject to change, in accordance with the Court's General Orders, upon review by the Court of your Complaint or Notice of Removal.

<b>Question A: Was this case removed from state court?</b> <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "no," go to Question B. If "yes," check the box to the right that applies, enter the corresponding division in response to Question D, below, and skip to Section IX.	<b>STATE CASE WAS PENDING IN THE COUNTY OF:</b>		<b>INITIAL DIVISION IN CACD IS:</b>
	<input type="checkbox"/> Los Angeles		Western
	<input type="checkbox"/> Ventura, Santa Barbara, or San Luis Obispo		Western
	<input type="checkbox"/> Orange		Southern
	<input type="checkbox"/> Riverside or San Bernardino		Eastern

<b>Question B: Is the United States, or one of its agencies or employees, a party to this action?</b> <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "no," go to Question C. If "yes," check the box to the right that applies, enter the corresponding division in response to Question D, below, and skip to Section IX.	<b>If the United States, or one of its agencies or employees, is a party, is it:</b>		<b>INITIAL DIVISION IN CACD IS:</b>
	<b>A PLAINTIFF?</b> Then check the box below for the county in which the majority of DEFENDANTS reside.	<b>A DEFENDANT?</b> Then check the box below for the county in which the majority of PLAINTIFFS reside.	
	<input type="checkbox"/> Los Angeles	<input type="checkbox"/> Los Angeles	Western
	<input type="checkbox"/> Ventura, Santa Barbara, or San Luis Obispo	<input type="checkbox"/> Ventura, Santa Barbara, or San Luis Obispo	Western
	<input type="checkbox"/> Orange	<input type="checkbox"/> Orange	Southern
	<input type="checkbox"/> Riverside or San Bernardino	<input type="checkbox"/> Riverside or San Bernardino	Eastern
	<input type="checkbox"/> Other	<input type="checkbox"/> Other	Western

<b>Question C: Location of plaintiffs, defendants, and claims? (Make only one selection per row)</b>	<b>A. Los Angeles County</b>	<b>B. Ventura, Santa Barbara, or San Luis Obispo Counties</b>	<b>C. Orange County</b>	<b>D. Riverside or San Bernardino Counties</b>	<b>E. Outside the Central District of California</b>	<b>F. Other</b>
Indicate the location in which a majority of plaintiffs reside:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Indicate the location in which a majority of defendants reside:	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Indicate the location in which a majority of claims arose:	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**C.1. Is either of the following true? If so, check the one that applies:**

- ☒ 2 or more answers in Column C  
☐ only 1 answer in Column C and no answers in Column D

Your case will initially be assigned to the  
SOUTHERN DIVISION.  
Enter "Southern" in response to Question D, below.

If none applies, answer question C.2 to the right. →

**C.2. Is either of the following true? If so, check the one that applies:**

- ☐ 2 or more answers in Column D  
☐ only 1 answer in Column D and no answers in Column C

Your case will initially be assigned to the  
EASTERN DIVISION.  
Enter "Eastern" in response to Question D, below.

If none applies, go to the box below. ↓

Your case will initially be assigned to the  
WESTERN DIVISION.  
Enter "Western" in response to Question D below.

<b>Question D: Initial Division?</b>	<b>INITIAL DIVISION IN CACD</b>
Enter the initial division determined by Question A, B, or C above: →	Southern Division



**UNITED STATES DISTRICT COURT, CENTRAL DISTRICT OF CALIFORNIA  
CIVIL COVER SHEET**

**IX(a). IDENTICAL CASES:** Has this action been previously filed in **this court** and dismissed, remanded or closed? ☒ NO ☐ YES

If yes, list case number(s): \_\_\_\_\_

**IX(b). RELATED CASES:** Have any cases been previously filed in **this court** that are related to the present case? ☒ NO ☐ YES

If yes, list case number(s): \_\_\_\_\_

**Civil cases are deemed related if a previously filed case and the present case:**

(Check all boxes that apply)

- ☐ A. Arise from the same or closely related transactions, happenings, or events; or
- ☐ B. Call for determination of the same or substantially related or similar questions of law and fact; or
- ☐ C. For other reasons would entail substantial duplication of labor if heard by different judges; or
- ☐ D. Involve the same patent, trademark or copyright, and one of the factors identified above in a, b or c also is present.

**X. SIGNATURE OF ATTORNEY**

**(OR SELF-REPRESENTED LITIGANT):** *K. Holland*

DATE: 1/7/2014

**Notice to Counsel/Parties:** The CV-71 (JS-44) Civil Cover Sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law. This form, approved by the Judicial Conference of the United States in September 1974, is required pursuant to Local Rule 3-1 is not filed but is used by the Clerk of the Court for the purpose of statistics, venue and initiating the civil docket sheet. (For more detailed instructions, see separate instructions sheet).

Key to Statistical codes relating to Social Security Cases:

Nature of Suit Code	Abbreviation	Substantive Statement of Cause of Action
861	HIA	All claims for health insurance benefits (Medicare) under Title 18, Part A, of the Social Security Act, as amended. Also, include claims by hospitals, skilled nursing facilities, etc., for certification as providers of services under the program. (42 U.S.C. 1935FF(b))
862	BL	All claims for "Black Lung" benefits under Title 4, Part B, of the Federal Coal Mine Health and Safety Act of 1969. (30 U.S.C. 923)
863	DIWC	All claims filed by insured workers for disability insurance benefits under Title 2 of the Social Security Act, as amended; plus all claims filed for child's insurance benefits based on disability. (42 U.S.C. 405 (g))
863	DIWW	All claims filed for widows or widowers insurance benefits based on disability under Title 2 of the Social Security Act, as amended. (42 U.S.C. 405 (g))
864	SSID	All claims for supplemental security income payments based upon disability filed under Title 16 of the Social Security Act, as amended.
865	RSI	All claims for retirement (old age) and survivors benefits under Title 2 of the Social Security Act, as amended. (42 U.S.C. 405 (g))

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**IN THE COURT OF COMMON PLEAS  
FOR MONTGOMERY COUNTY, PENNSYLVANIA**

<p><b>INTERNATIONAL UNION OF OPERATING ENGINEERS LOCAL 542</b></p> <p style="text-align: center;">Plaintiff,</p> <p style="text-align: center;">v.</p> <p><b>MALLINCKRODT ARD, INC., <i>et al.</i></b></p> <p style="text-align: center;">Defendants.</p>	<p>Civil Action No. 2018-14059</p>
---	------------------------------------

**CERTIFICATE OF SERVICE**

I, Donald E. Haviland, Jr. hereby certify that on this 27th day of August, 2018, a true and correct copy of Plaintiff's Amended Civil Action Complaint was electronically filed, causing service to be made through the Court's ECF system as follows:

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s/ Donald E. Haviland, Jr.  
Donald E. Haviland, Jr., Esq.

# EXHIBIT 2

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*Counsel for Plaintiff,  
Steamfitters Local Union No. 420 and the Class*

**STEAMFITTERS LOCAL UNION NO. 420,**  
*individually and on behalf of all others  
similarly situated,*  
14420 Townsend Road  
Philadelphia, PA 19154

Plaintiff,

v.

**MALLINCKRODT ARD, LLC,**  
*f/k/a Mallinckrodt ARD, Inc.;*  
*f/k/a Questcor Pharmaceuticals, Inc.;*  
1425 U.S. Route 206  
Bedminster, NJ 07921

**UNITED BIOSOURCE CORPORATION,**  
*now known as UNITED BIOSOURCE LLC,*  
*a wholly owned subsidiary of UNITED*  
**BIOSOURCE HOLDINGS, INC.**  
920 Harvest Drive  
Blue Bell, PA 19422

Defendants.

IN THE UNITED STATES DISTRICT  
COURT FOR THE EASTERN  
DISTRICT OF PENNSYLVANIA

CIVIL ACTION NO. \_\_\_\_\_

**CIVIL CLASS ACTION COMPLAINT**

**JURY TRIAL DEMANDED**

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## **CIVIL CLASS ACTION COMPLAINT**

Plaintiff, Steamfitters Local Union No. 420 (***“Local 420” or “Plaintiff”***), by and through its undersigned counsel, individually and on behalf of all other third-party payors (“TPPs”) and their beneficiaries similarly situated, alleges as follows:

### **I. NATURE OF THE CASE**

1. Steamfitters Local Union No. 420 brings this action on behalf of itself, its beneficiaries, and all other TPPs and their beneficiaries similarly situated, to challenge the unjust, unfair and deceptive marketing and sales scheme and conspiracy by Defendants, Mallinckrodt ARD LLC, formerly known as Mallinckrodt ARD, Inc., and, prior to that, formerly named Questcor Pharmaceuticals, Inc. (***“Questcor”***)(collectively ***“Mallinckrodt”***), along with its named and unnamed co-conspirators as further described herein. Specifically, Plaintiff names United BioSource Corporation n/k/a United BioSource LLC (***“UBC”***) for its direct role in the scheme and conspiracy alleged.

2. Mallinckrodt manufactures, markets, distributes and sells H.P. Acthar Gel, NDC Nos. 63004-8710-01 and 63004-7731-01 (***“Acthar”***). Acthar is the only therapeutic ACTH product sold in the United States. Mallinckrodt is the sole provider of Acthar in the U.S.

3. Mallinckrodt acquired Acthar in July 2001, when Questcor purchased Acthar from Aventis Pharmaceutical Products Inc. for \$100,000.

4. Acthar is a “specialty pharmaceutical”. Unlike most prescription drugs, it is not sold in retail pharmacies, nor is it distributed through wholesalers to retail pharmacies. Instead, it is distributed only through “specialty pharmacy distributors” (***“SPDs”***) and “specialty pharmacy providers” (***“SPPs”***).

5. While there are dozens of SPDs and SPPs in America, one of the largest SPDs is



CuraScript, Inc., doing business as CuraScript SD, and Priority Healthcare Corp, also doing business as CuraScript SD (collectively, “**CuraScript**”). One of the largest SPPs is Accredo Health Group, Inc. (“**Accredo**”). Express Scripts, Inc. has owned both CuraScript and Accredo since 2004. Express Scripts also owned UBC, and its predecessor entity HealthBridge, from 2007 through the end of 2017.

6. In 2007, Mallinckrodt decided to embark on a self-described “new strategy” with respect to the distribution, pricing, marketing and sales of Acthar. The mastermind of this new strategy was Gregg LaPointe, a member of Questcor’s Board of Directors at the time, who joined with Steve Cartt, Questcor’s Chief Operating Officer, to convince another Board member, Don Bailey, that the strategy should be implemented, over the objections of the existing Questcor CEO and several Board members and executives.

7. The new strategy had three essential components to it. These three components comprise the schemes that underscore the RICO enterprises and unfair and deceptive acts and practices at issue in this case.

8. First, Mallinckrodt changed the way it distributed and sold Acthar (the “**Distribution Scheme**”). It limited the distribution of Acthar from multiple distribution outlets to just one, CuraScript, and engaged UBC to act as its exclusive “HUB” of operations controlling both the distribution and reimbursement of Acthar directly with patients and TPPs. (CuraScript and UBC were both subsidiaries of Express Scripts.) Mallinckrodt created this exclusive distribution arrangement to limit and control distribution and output of Acthar, and to raise the prices of Acthar to unconscionable levels. Mallinckrodt and UBC created the Acthar Support and Access Program (“ASAP”) described below as the vehicle to effectuate their Distribution Scheme.

9. While this conduct constitutes antitrust, and is the subject of a separate federal class action lawsuit pending in Rockford, Illinois<sup>1</sup>, it is also the subject of separate *qui tam* lawsuits brought in this Court by former employees of Mallinckrodt, in which the federal government has intervened. See *U.S. ex. Rel. Charles Strunck and Lisa Pratta v. Mallinckrodt ARD, Inc., et al.* 2:12-cv-00175-BMS (E.D.Pa.) at Document No. 40 (“*Strunck & Pratta Complaint*”); *U.S. ex. Rel. Scott Clark v. Questcor Pharmaceuticals, Inc.*, 2:13-cv-01776-BMS (E.D.Pa.) at Document 1 (“*Clark Complaint*”).

10. Local 420 brings no overlapping claims against Mallinckrodt or UBC in this lawsuit for any alleged antitrust violations. Instead, it sues on behalf of itself and all similarly situated TPPs of Acthar for consumer fraud, RICO violations and other common law claims arising out of the unique distribution, pricing, marketing and sales schemes alleged herein, arising out of the unique claims alleged by several former employees of Mallinckrodt. The details of the conduct underlying these claims were only first revealed to Plaintiff and the Class in April 2019 when the *Strunck and Pratta Complaint* was unsealed by this Court.

11. Second, throughout the relevant time period, since August 2007 through the present, Mallinckrodt has willfully manipulated and inflated the prices paid by TPPs for Acthar, causing TPPs like Local 420 to substantially overpay for a drug with very limited uses and benefits and an unknown method of action (the “**Pricing Scheme**”). Specifically, after limiting Acthar distribution by the Distribution Scheme, in August 2007, Mallinckrodt agreed with CuraScript and UBC to raise the average wholesale prices (“**AWPs**”) paid for Acthar by TPPs like Local 420 from \$2,062.79 per vial to \$29,086.25, a more than 1,300% increase in the cost of Acthar in the span of one month. Such a price increase is both unprecedented and

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<sup>1</sup> See *City of Rockford v. Mallinckrodt ARD, Inc., et. al.*, Case No. 17-cv-50107 (N.D.Ill.) (hereinafter the “**Rockford case**”).

unconscionable, especially for a more than 65-year old drug. Mallinckrodt, Curascript and UBC have continued to raise the AWP for Acthar each year, sometimes by double-digit percentages, such that now a drug that once cost \$40.00 costs patients and third-party payors over \$43,000.00. The only way Mallinckrodt has been able to get TPPs to pay such high prices for Acthar was through the fraudulent schemes alleged herein. But for such schemes, TPPs like Local 420 would not have paid what they did for Acthar.

12. Third, Mallinckrodt and UBC devised a marketing and sales scheme designed to ensure that Acthar was reimbursed by TPPs at the new, inflated AWP, without substantial backlash from patients and payors (the “**Marketing Scheme**”). Fearing an uproar of complaints from patients, patient support groups, private TPPs and the federal government for their unjustified distribution limitations and price increases, and in order to circumvent TPP cost containment mechanisms for high-priced specialty drugs, Mallinckrodt devised a multi-faceted scheme and RICO enterprise to bribe doctors in order to induce them to prescribe Acthar over other available treatments. The scheme involved cultivating key opinion leaders (or “KOLs”) from around the country to serve as the company’s “spokes-doctors” in promoting prescriptions of Acthar for unapproved uses and doses. The scheme also sought to remove patient complaints about high co-pays on Acthar by funneling tens of millions of dollars to UBC to run a so-called “patient assistance program” or “PAP” designed to ensure that private TPPs paid the bulk of the costs of Acthar.

13. On April 30, 2019, it was revealed publically for the first time by CNN<sup>2</sup> that two whistleblowers, both former pharmaceutical sales representatives for Mallinckrodt, had sued the company years before for a “multi-tiered strategy” to boost sales by bribing doctors to prescribe

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<sup>2</sup> <https://www.cnn.com/2019/04/30/health/mallinckrodt-whistleblower-lawsuit-acthar/index.html>

the high-priced Acthar to their patients. As described more fully in the *Strunck & Pratta Complaint*, Mallinckrodt's scheme involved "using valuable incentives, rewards and other forms of remuneration to induce health care providers to promote and prescribe H.P. Acthar in lieu of less expensive therapies that are equally more effective...". *Strunck & Pratta Cmplt.* at ¶ 3(i). According to Strunck and Pratta, there is a pervasive culture at Mallinckrodt designed to sell Acthar at all costs.

14. Separately, a different whistleblower sued Mallinckrodt in this Court on April 4, 2013, alleging a different aspect of Mallinckrodt's scheme to sell Acthar at high prices. In a case unsealed as part of the government's filing of a consolidated, amended pleading, former employee Scott Clark alleges that "Mallinckrodt designed supposed 'patient assistance' funds that paid copays for Acthar only and then funded them through 'donations', knowing its money would be used on Acthar copays to the exclusion of other drugs." *See United States' Complaint in Intervention*, Dkt No. 2:13-cv-01776-BMS (E.D.Pa.) (BMS) at Document No. 57 ("*U.S. Complaint*") at ¶ 5. Such conduct is unlawful.

15. As the federal government has alleged:

"Mallinckrodt knew that the cost of Acthar would make it difficult to sell because there were cheaper, effective competitor drugs available to treat certain of its approved uses, namely acute exacerbations in multiple sclerosis, lupus and rheumatoid arthritis. Mallinckrodt intended to overcome this difficulty and did so by making the drug 'free' to patients by subsidizing their Medicare [and private] copayments. By doing so, Mallinckrodt could maintain the high price of Acthar to maximize its own sales revenues, but minimize the risk that the drug's high price would impede doctors and patients from using it."

*Id.* at ¶ 4 (brackets added).

16. Accordingly, in conjunction with limiting Acthar distribution and raising the prices for Acthar in 2007, as part of the Distribution and Pricing Schemes, Mallinckrodt also

embarked on a Marketing Scheme designed to incentivize sales of Acthar at the new high prices. Patients and TPPs had no choice but to pay the high prices charged by Mallinckrodt and UBC, Mallinckrodt's exclusive agent and "HUB".

17. Mallinckrodt vastly expanded its direct-to-consumer selling of Acthar by expanding its sales force, including creating a team of "medical science liaisons" or "MSLs". The MSLs were highly trained specialists in the Acthar treatments who worked with other Mallinckrodt sales representatives to create a network of KOLs. These KOLs were leading specialists in their respective medical fields whom Mallinckrodt identified as being potentially influential on other doctors. These KOLs were paid handsomely to join with Mallinckrodt's MSLs and sales representatives as "spokes-doctors", promoting Acthar to other medical providers and delivering Mallinckrodt's false, misleading and deceptive promotional messages about the safety, efficacy and value of Acthar in relation to other cheaper, safer, and equally or more effective treatments. As a result, thousands of new patients have been prescribed Acthar for unapproved uses and doses in the treatment of diseases in neurology, nephrology and rheumatology, among others. And TPPs have been forced to pay the exorbitant prices charged by Defendants.

18. Local 420, other TPPs who have sued in state courts,<sup>3</sup> and the Class of TPPs and their beneficiaries were harmed by Mallinckrodt's conduct. Specifically, in 2018, Local 420 paid for Acthar at the inflated prices charged by Defendants as a result of the Distribution, Pricing, and Marketing Schemes alleged. To date, Local 420 has paid \$152,798.92 for Acthar, more than it otherwise would have paid in the absence of Mallinckrodt's scheme and conspiracy.

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<sup>3</sup> One such TPP is the International Union of Operating Engineers Local 542 ("IUOE Local 542") based in Fort Washington, Pennsylvania. IUOE Local 542 sued Mallinckrodt and UBC in the Court of Common Pleas for Montgomery County, Pennsylvania in May 2018.

19. Local 420 brings this lawsuit on behalf of itself and a Class of all similarly-situated TPPs and their beneficiaries who paid for Acthar at prices based on the inflated AWP prices set by Mallinckrodt during the relevant time period between August 2007 and the present. Because some of the TPPs in the Class have already sued Mallinckrodt in state courts on their individual claims, Local 420 seeks to obtain declaratory and injunctive relief in this Court on behalf of a nationwide Class of all TPPs, in order to have the conduct of Defendants declared unlawful and enjoined, for the benefit of all affected TPPs and their beneficiaries. Local 420 also seeks to recover money damages for overpayments based on inflated AWP prices for Acthar, pursuant to federal RICO and the consumer protection laws of Pennsylvania and other states, as well as the common law of Pennsylvania and other states. Finally, Plaintiff seeks punitive damages for the Defendants' willful, outrageous and reckless conduct.

## **II. JURISDICTION AND VENUE**

20. This Court has subject matter jurisdiction over this action pursuant to the Class Action Fairness Act of 2005, 28 U.S.C. § 1332(d), because Local 420 and members of the Class are diverse from the Defendants and over two-thirds of the Class is situated outside of Pennsylvania. Due to the exorbitant prices charged by Defendants for Acthar to the Class – currently over \$43,000.00 per prescription for a drug that used to cost a little more than \$2,000 -- the aggregate amount in controversy far exceeds \$5,000,000 for the Class.

21. This Court has personal jurisdiction over Plaintiff because it is located in Pennsylvania and it reimbursed for Acthar and other drugs in Pennsylvania.

22. This Court has jurisdiction over the Defendants because they are present and/or conduct substantial business in Pennsylvania, have registered to conduct business here, have had systematic and continuous contacts with Pennsylvania, and/or have agents and representatives

that can be found in Pennsylvania. The Court also has jurisdiction over multiple, unnamed co-conspirators who assisted Mallinckrodt in carrying out its scheme, including sales representatives, MSLs, and KOLs located in Pennsylvania as described herein.

23. The Court also has jurisdiction over the Defendants because they have had sufficient minimum contacts with and/or have purposefully availed themselves of the laws and markets of Pennsylvania through, among other things, their distribution, marketing and sales of Acthar to Local 420 and other residents of Pennsylvania.

24. Venue is proper in this District because Local 420 is situated in this District, and the Defendants transact business in this District. Venue is also proper because a substantial part of the events giving rise to Local 420's claims occurred in this District. Defendants also engaged in substantial conduct relevant to the claims of Local 420 and the Class, and caused harm to members of the Class in this District. Venue is also proper pursuant to 28 U.S.C. §1391.

25. Acthar is sold in both interstate and intrastate commerce, and the unlawful activities alleged in this Complaint have occurred in Pennsylvania and this District.

### **III. THE PARTIES**

#### **A. PLAINTIFF**

26. Local 420 is a Taft-Hartley union fund providing health and welfare benefits to its members and their families. Local 420 has a business address at 14420 Townsend Road, Philadelphia, Pennsylvania 19154, which is situated in Philadelphia County, Pennsylvania.

27. Local 420 has represented the interests of working men and women in eastern Pennsylvania since 1935, including heavy equipment operators in the building and construction industry, along with C & D-Branch Division members who are employed at quarries, landfills, equipment dealers, shipyards, breweries, manufacturing plants, airports, bridges, and public



works.

28. Local 420 provides healthcare benefits to its employees through Independence Blue Cross (“IBC”). While IBC coordinates Local 420’s prescription drug benefits, including specialty drugs like Acthar, through Future Scripts, a pharmacy benefits manager (“PBM”), Local 420 is self-funded, meaning that Local 420 and its beneficiaries pay the full costs of drugs like Acthar.

29. The spouse of one such member of Local 420 has a medical condition, a rheumatic disorder, for which Acthar was prescribed for treatment. As described more fully herein, rheumatic conditions became a target of Defendant’s marketing and sales scheme to promote the sale of Acthar at artificially inflated prices. She received four separate prescriptions of Acthar in early 2018. Local 420 then paid for these administrations of Acthar at a net cost of \$38,199.73 for each such prescription. The net cost was based upon the inflated AWP of Acthar as set by Mallinckrodt.

30. The sum total of the 4 prescriptions paid for by Local 420 was \$152,798.92. The member/beneficiary was required to pay a co-pay of \$70.00 for each prescription, for a total of \$280.00. As a result, Local 420 has incurred a financial harm due to the Defendants’ conduct stated herein.

## **B. DEFENDANTS**

31. Defendant Mallinckrodt ARD LLC (“Mallinckrodt”) has its principal place of business at 1425 U.S. Route 206, Bedminster, New Jersey 07921. Mallinckrodt ARD LLC was previously named Mallinckrodt ARD, Inc., and before that was named Questcor Pharmaceuticals, Inc. (“Questcor”).

32. Mallinckrodt ARD LLC is an indirect wholly-owned subsidiary of Mallinckrodt



plc, an Irish public limited company, with its corporate headquarters in Staines-upon-Thames, United Kingdom.

33. On April 4, 2014, Mallinckrodt plc entered into an Agreement and Plan of Merger with Questcor and effectuated the acquisition of Questcor on August 14, 2014 for approximately \$5.9 billion.

34. Following the merger, Questcor continued to market and sell Acthar, until changing its name to Mallinckrodt ARD Inc. on July 27, 2015.

35. On January 26, 2019, Mallinckrodt ARD, Inc. converted to Mallinckrodt ARD LLC and continues to market Acthar under that name today.

36. Defendant United BioSource Corporation n/k/a United BioSource LLC (“UBC”) is a Delaware corporation with its corporate headquarters at 920 Harvest Drive, Blue Bell, Pennsylvania 19422. UBC has been a wholly-owned subsidiary of Express Scripts from 2007, when it was known as HealthBridge. In 2012, UBC was acquired by Express Scripts as part of the Medco merger, and HealthBridge was renamed UBC. In November 2017, Express Scripts announced that it sold UBC to Avista Capital Partners, a private equity firm.

37. UBC is a wholly owned subsidiary of United BioSource Holdings, Inc., the interests of which are held by and through various privately held intermediary entities, which are ultimately owned by private investment funds sponsored by and/or affiliated with Avista Capital Partners and as-yet-unknown individuals associated with Avista Capital Partners.

38. UBC is Mallinckrodt’s exclusive “agent” designated to operate the Acthar Support and Access Program (“ASAP”), a program put in place in 2007 as part of the “new strategy” to manage the Acthar’s exclusive distribution and sales directly to patients. UBC is specifically identified as Mallinckrodt’s agent on the Acthar Start Form, which every patient and

health care provider (“HCP”) is required to fill out and sign prior to receiving Acthar. *See* 2018 Acthar Start Form at **Exhibit “A” hereto**.

39. UBC operates as the Mallinckrodt’s “HUB” of operations for Acthar distribution and payment, coordinating all aspects of the scheme and conspiracy, from the initial identification of patients, insurance and payment verification, through to payment by TPPs, like Local 420 and the Class.

40. The corporate Defendants’ acts alleged in this Complaint to have been done by each of the Defendants were authorized, ordered, done and/or ratified by their respective officers, directors, agents, employees or representatives while engaged in the management, direction, control or transaction of their respective business affairs.

#### **IV. FACTUAL BACKGROUND**

##### **A. ACTHAR DEVELOPMENT AND LIMITED APPROVAL BY THE FDA**

41. Acthar was approved by the FDA on April 29, 1952 for over 50 conditions, ranging from alcoholism, poison ivy, and radiation sickness to nephrotic syndrome. Over time, as discussed below, with additional evidence-based requirements for prescription drugs, the list was winnowed by the FDA to the fewer, present-day 19 indications.

42. Acthar is adrenocorticotrophic hormone (“ACTH”), which causes the body to produce cortisone and other steroid hormones. Two Mayo Clinic researchers, Drs. Philip Hench and Edward Kendall, developed the treatment, which won them the Nobel Prize for medicine at the time it was developed.

43. Acthar was developed by Armour Pharmaceutical Company. As described by the Seventh Circuit in *Armour & Co. v. Wilson & Co.*, 274 F.2d 143, 145-46 (7th Cir. 1960):

In a human being, . . . (ACTH) appears in the anterior lobe of the pituitary gland located at the base of the brain. When the human

body is under stress or attacked by certain diseases, control centers in the brain excite the pituitary, and the pituitary secretes ACTH. In the blood stream the ACTH thus secreted is carried to the adrenal glands situated in the human body above the kidneys. As the ACTH hits the outer wall of the adrenal glands, it stimulates the adrenals to produce a set of chemical substances such as steroids, including the hormones, cortisone and hydrocortisone.

The cortisone hormones then act in the tissues of the body to suppress inflammations and allergic reactions. ACTH thus is used to relieve such conditions as rheumatoid arthritis and allergies. ACTsH does not, itself, directly attack disease. However, it stimulates the adrenals which produce more than twenty-eight steroids, and these hormones attack the diseased tissues. When the human body itself does not supply sufficient ACTH, pharmaceutical ACTH can fill the gap.

44. In layman's terms, ACTH is a hormone released by the brain that triggers the adrenal glands to make cortisol, which is the body's equivalent of prednisone, a steroid. ACTH works by inducing a patient's adrenal glands to release cortisol, thereby replicating the effect of taking prednisone. Because of this, ACTH has risks and benefits similar to those of prednisone.

**1. The FDA Regulates What Drugs May Be Marketed, and the Uses For Which They May Be Marketed.**

45. Under FDCA 21 U.S.C. §§ 301-97, new pharmaceutical drugs cannot be marketed in the United States unless the sponsor of the drug demonstrates to the satisfaction of the FDA that the drug is safe and effective for each of its intended uses. 21 U.S.C. § 355(a), (d). Approval of the drug by the FDA is the final step in a multi-year process of study and testing.

46. To determine whether a drug is "safe and effective," the FDA relies on information provided by a drug's manufacturer; it does not conduct any substantial analysis or studies itself. Applications for FDA approval (known as New Drug Applications or "NDAs") must include "full reports of investigations which have been made to show whether or not such drug is safe for use and whether or not such drug is effective in use." 21 U.S.C. § 355(b)(1)(A).

47. Under the nation's food and drug laws, a drug may not be introduced into interstate commerce unless its sponsor has shown that the drug is safe and effective for the intended conditions of use. 21 U.S.C. §321. The law requires that "adequate and well controlled investigations" be used to demonstrate a drug's safety and effectiveness. 21 U.S.C. § 355(d)(7). The FDA approves a drug if there are "adequate and well-controlled clinical trials" that demonstrate a drug's safety and effectiveness for its "intended conditions" of use. 21 U.S.C. § 355(d)(5). The "intended conditions" for use of a drug are listed in the drug's labeling, which is reviewed and approved by the FDA. 21 U.S.C. § 355(d)(1) & (2). Indications for use that are not listed in a drug's labeling have not been approved by the FDA. 37 Fed. Reg. 16,503 (1972). They are "unapproved" uses.

48. The standards that govern the FDA safety and effectiveness requirements are contained in statutes, regulations, notices and guidance documents. The statutory requirement that a drug's effectiveness be demonstrated by "adequate and well-controlled clinical investigations" has been interpreted to mean a clinical study with (1) clear objectives; (2) adequate design to permit a valid comparison with a control group; (3) adequate selection of study subjects; (4) adequate measures to minimize bias; and (5) well defined and reliable methods of assessing subjects' responses to treatment. 21 C.F.R. § 314.26.

49. The FDA also requires the need for reproducibility and reliability of clinical data in the trials that support a drug's approval. In order to address this requirement, the FDA generally requires two pivotal, adequate and well-controlled trials to support approval, except in certain circumstances. As stated by the FDA in its 1998 Guidance to the Industry, "it has been FDA's position that Congress generally intended to require at least two adequate and well controlled studies, each convincing on its own, to establish effectiveness." *See* U.S. Department

of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (CDER), Center for Biologics Evaluation and Research (CBER), Guidance for Industry: Providing Clinical Evidence of Effectiveness for Human Drugs and Biological Products, May 1998. *See also, Final Decision on Benylin*, 44 FR 51512, 518 (Aug. 31, 1979).

50. The FDA's position is based on the language in the statute and the legislative history of the 1962 amendments. Language in a Senate report suggested that the phrase "adequate and well-controlled investigations" was designed not only to describe the quality of the required data but also the "quantum" of required evidence. *See* S. Rep. No. 1744, Part 2, 87<sup>th</sup> Cong.2d Sess. 6 (1962).

51. In Section 115(a) of the Medicare Modernization Act, Congress amended section 505(d) of the Act to make it clear that the FDA may consider "data from one adequate and well-controlled clinical investigation and confirmatory evidence" to constitute substantial evidence if the FDA determines that such data and evidence are sufficient to establish effectiveness. In making this clarification, Congress confirmed FDA's interpretation of the statutory requirements for approval and acknowledged the FDA's position that there has been substantial progress in the science of drug development resulting in higher quality clinical trial data.

52. Cases in which the FDA has approved a drug on the basis of one clinical trial plus, confirmatory evidence are rare. They include instances of large, independently conducted multi-center trials with strong empirical results, with internal consistency across multiple outcomes, such that "sponsors faced ethical boundaries" in conducting a second placebo-based trial. Clinical trials that are not controlled, blinded, randomized and whose endpoints are not prospectively and objectively determined and measured may be used in early stage drug

development phases, but are exceptionally unlikely to qualify as “adequate and well-controlled” clinical trials needed to support FDA approval.

53. After a drug is approved, the FDA continues to exercise control over the product labeling. To protect patients from safety concerns, the FDA may require a label change to reflect the increased risk of various side effects or interactions, restrict a drug's indications, or, in extreme cases, force a withdrawal from the market. 21 C.F.R. § 201.57(3).

**2. FDA Regulations Prohibit Off Label Marketing Through False and Misleading Statements About a Drug's Use or Benefits.**

54. FDA regulations restrict how drug companies may market and promote approved drugs. *See* 21 U.S.C. §§ 331, 852; 21 C.F.R. § 314.81. Drug labels, including all marketing and promotional materials relating to the drug, may not describe intended uses for the drug that have not been approved by the FDA. 21 U.S.C. §§ 331; 352. Illegal “misbranding” can result in criminal penalties. 21 U.S.C. § 333.

55. Drug companies such as Mallinckrodt must submit specimens of mailing pieces and any other labeling or advertising devised or used for promotion of the drug product at the time of initial dissemination of the labeling and at the time of initial publication of the advertisement for a prescription drug product. Each submission is required to be accompanied by a completed transmittal Form FDA-2253. This constitutes a specific and material representation that all promotional items are being disclosed and provided to the FDA. Moreover, it constitutes an implied representation that the promotion and marketing that is being done through verbal communications, including inter alia, any drug company's speech or “advertisement” for the product, which are also subject to the prohibitions against off label marketing in 21 C.F.R. 202.1, is consistent and in line with any written communications being submitted to FDA.

56. The same general requirements about the promotion of prescription drugs apply to both professional and consumer-oriented marketing. In particular, promotional materials may only make claims that are supported by “substantial” scientific evidence (according to strict scientific procedures) and they may not be false, deceptive or misleading. FDA oversight helps ensure a “fair balance” in all promotional claims and materials. Federal regulations require that the risks as well as the benefits be clearly identified and given appropriate prominence. Promotional materials must be consistent with the FDA-approved product labeling. This restriction pertains to the clinical indications for which the drug has been approved as well as the dosing regimen that is supported by the clinical trials that were undertaken to establish safety and efficacy.

57. A drug company that wishes to market or otherwise promote an approved drug for uses other than those listed on the approved label, must resubmit the drug for a series of clinical trials similar to those required for the initial FDA approval. *See* Food and Drug Administration Modernization Act of 1997 (“FDMA”) 21 U.S.C. §§ 360aaa(b), (c); *see also* 21 C.F.R. § 814.54 (outlining the administrative procedure for filing an application for a new indication); 21 U.S.C. §§ 301, *et seq.* A supplemental NDA must be filed. Unless and until an additional indication is approved by the FDA, the unapproved use is considered to be “off-label.”

58. The term “off-label” refers to the use of an approved drug for any purpose, or in any manner, other than what is described in the drug's labeling. Off-label use includes treating a condition not indicated on the label, treating the indicated condition at a different dose or frequency than specified on the label, or treating a different patient population, *e.g.*, treating a child when the drug is approved to treat adults.



59. Although the FDA is responsible for ensuring that a drug is safe and effective for the specific approved indication, the FDA does not regulate the practice of medicine. Once a drug is approved for a particular use, the FDA does not prohibit physicians from prescribing the drug for uses that are different than those approved by the FDA. When considering off-label prescribing, physicians are supposed to depend on the patient-specific evidence they have available to them. This should include the particular patient, the severity of his or her problems, the successfulness of prior treatment, and the risks of not treating. Whether contemplating on or off-label use, physicians also sometimes rely on personal experience, recommendations from colleagues and academics, educational seminars, and clinical trials evidence. Regrettably, much of what physicians rely on is information (or, as the case may be, misinformation) provided by sales representatives from drug makers, drug company sponsored continuing medical education (“CME”) courses and speaker programs, and drug company sponsored clinical trials.

60. Although physicians may prescribe drugs for off-label usage, the law prohibits drug manufacturers from marketing or promoting a drug for a use that the FDA has not approved, or for a patient group that is unapproved. Specifically, a manufacturer illegally “misbrands” a drug if the drug's labeling (which includes all marketing and promotional materials relating to the drug) describes intended uses for the drug that have not been approved by the FDA. 21 U.S.C. §§ 331, 352. The statute, 21 U.S.C. § 331(d), and its implementing regulations, and 21 C.F.R. 202.1(e)(4)(i)(a) prohibit any advertising that recommends or suggests an off-label use for an approved drug, and the FDA has interpreted “advertising” to include a significant amount of speech that would not typically be considered advertising. *See* Final Guidance on Industry-Supported Scientific and Educational Activities, 62 Fed. Reg. 64,074 (Dec. 3, 1997). The FDA “interprets the term ‘advertisement’ to include information (other than



labeling) that originates from the same source as the product and that is intended to supplement or explain the product.”

61. Any drug company's speech explaining one of its products is an “advertisement” for the product and is subject to the prohibitions against off label marketing in 21 C.F.R. 202.1, as well as the FDA’s “fair balance” requirement, described below. While a drug company may be entitled to certain First Amendment protection for truthful speech, *see U.S. v. Caronia*, 703 F.3d 149 (2d. Cir. 2012), off-label promotion that is false or misleading is not entitled to First Amendment protection. *Caronia*, 703 F.3d at 166 n. 10. *See Cent. Hudson*, 447 U.S. at 566, 100 S. Ct. 2343. Under 21 U.S.C. § 331(a), a defendant may be prosecuted for untruthfully promoting the off-label use of an FDA approved drug, *e.g.*, making false or misleading statements about a drug.

62. Section 202.1(e)(6)(xi) provides that an advertisement may not use “literature, quotations, or references for the purpose of recommending or suggesting conditions of drug use that are not approved or permitted in the drug package labeling.” *See also* 21 U.S.C. § 331(d) (prohibiting distribution of a drug for non-approved uses); *id.* at § 331(a) (prohibiting distribution of a misbranded drug); *id.* at § 360aaa (permitting dissemination of material on off-label uses only if the manufacturer meets certain stringent requirements).

63. The FDA regulations that fall under the general rubric of 21 C.F.R. 202.1(e)(6), *et seq.* ban advertisements that are false, lacking in fair balance, or otherwise misleading. Thus, the use of unsubstantiated comparative claims also is prohibited by law. 21 U.S.C. § 352; 21 C.F.R. § 202.1(e)(6).

64. Thus, companies like Mallinckrodt may not promote their approved drugs through unsubstantiated comparative claims that exalt their drugs as safer or more efficacious than

competitor drugs. Such promotion renders a drug “misbranded” and no longer eligible for reimbursement by government programs, including Medicare and Medicaid.

65. The regulations prohibit an advertisement that “contains a representation or suggestion that a drug is safer than it has been demonstrated to be by substantial evidence or substantial clinical experience, by selective presentation of information from published articles or other references that report no side effects or minimal side effects with the drug or otherwise selects information from any source in a way that makes a drug appear to be safer than has been demonstrated.” 21 C.F.R. 202.1(e)(6)(iv).

66. The regulations require drug companies to present a “true statement” of information relating to the side effects, contraindications and effectiveness of the drug use. 21 C.F.R. 202.1(e)(5), *et seq.* A company violates this regulation if it presents “false or misleading” information about a drug's side effects or does not “fair[ly] balance” information relating to the safety and efficacy of the drug use against information about its side effects and contraindications. *Id.*

67. Section 202.1(1)(2) broadly describes “labeling” of a drug as including any material accompanying a drug product that is supplied and disseminated by the manufacturer, packer or distributor of the drug.

68. Section 201.56 requires labeling to be “informative and accurate and neither promotional in tone nor false and misleading in any particular,” to “contain a summary of the essential scientific information needed for the safe and effective use of the drug,” and prohibits “implied claims or suggestions of drug use if there is inadequate evidence of safety or a lack of substantial evidence of effectiveness.”

69. The FDA has interpreted oral communications as falling under the umbrella of “labeling.”

70. Section 99.101, *et seq.* lays out the stringent requirements that must be met by the manufacturer before it may disseminate any materials on unapproved or new uses of marketed drugs. This material must be in the form of an unabridged reprint or copy of a published, peer reviewed article that is considered “scientifically sound” by experts qualified to evaluate the safety or effectiveness of the drug involved. *See* 21 C.F.R. 99.101(a)(2). The FDA does not consider abstracts of publications to be “scientifically sound” 21 C.F.R. 99.101(b). Unabridged reprints or copies of articles shall not be disseminated with any information that is promotional in nature. 21 C.F.R. 99.101(b)(2).

71. Furthermore, the manufacturer must not disseminate materials that are “false and misleading,” such as those that only present favorable information when unfavorable publications exist, exclude mandatory information about the safety and efficacy of the drug use, or present conclusions that “clearly cannot be supported by the results of the study.” 21 C.F.R. 99.101(a)(4).

72. Additionally, off-label information may be disseminated only in response to an “unsolicited request from a healthcare practitioner.” 21 U.S.C. § 360aaa 6. In any other circumstance, a manufacturer may disseminate information concerning off-label use only after it has submitted an application to the FDA seeking approval of the drug for the off-label use, has provided the materials to the FDA prior to dissemination; and the materials themselves are submitted in unabridged form and are neither false or misleading. 21 U.S.C. §§ 360aaa (b) & (c); 360aaa 1.

73. The FDA does not generally regulate the exchange of scientific information, but when such information is provided by or on behalf of a drug company regarding one of the company's products, the information may be subject to the labeling and advertising provisions of the law and regulations. For example, while information provided at continuing medical education programs (such as medical conferences and professional gatherings intended to enhance physicians' knowledge and enable them to meet certain practice requirements) generally is not subject to FDA regulation, it will be subject to FDA regulation if the program has been funded and substantially influenced by a drug company.

74. In sum, the off label regulatory regime of the federal government protects patients and consumers by ensuring that drug companies do not promote drugs for uses other than those found to be safe and effective by an independent, scientific government body – the FDA. The prohibition on unsubstantiated comparative claims protects patients and consumers by ensuring that the prescription and use of approved drugs is not based on misleading marketing tactics.

**3. The FDA has limited ability to regulate drug company marketing and promotion.**

75. The FDA's Division of Drug Marketing, Advertising and Communications (“DDMAC”) is charged with overseeing the marketing and promotion of approved drugs to ensure that advertisements are not false or misleading, provide a fair balance between the benefits and risks of the drug, and do not include off label uses. *See* Statement by Janet Woodcock, M.D. (Director Center for Drug Evaluation and Research, FDA) Before the Senate Special Committee on Aging (July 22, 2003).

76. DDMAC's effectiveness in regulating off label promotion is limited. In 2003, the entire staff consisted of forty members, with twenty-five reviewers responsible for reviewing all drug advertisements and promotional materials. Moreover, drug materials do not have to be pre-

approved. FDA review of promotional materials occurs, if at all, only after the materials already have appeared in public. *See* Woodcock Statement, *supra*. Upon finding a violation, DDMAC generally requests, but does not require, the company to stop using the promotional materials. *Id.* Sponsors occasionally are required to publicly correct product misimpressions created by false, misleading, or unbalanced materials. *Id.*

77. Once a drug has been approved, the FDA's statutory authority is limited to requesting label changes, negotiating restrictions on distribution with the manufacturer, and petitioning for the withdrawal of the drug from the marketplace. Title 21 of the Code of Federal Regulations requires that "as soon as there is reasonable evidence of a serious hazard with a drug," the "Warnings" section of the label should be revised to reflect this hazard.

78. The FDA's ineffectiveness in policing off label promotion was confirmed in a July 28, 2008 U.S. General Accountability Office Report, which found that the FDA took an average of seven (7) months to issue letters in response to off-label promotions. *See* Drugs: FDA Oversight of the Promotion of Drugs for Off-Label Uses (GAO 08-835), <http://www.gao.gov/new.items/d08835.pdf>. Among the Report's findings: (i) FDA does not have separate oversight activities to specifically capture off-label promotion; (ii) FDA is unable to review all promotional submissions because of the volume of materials it receives and prioritizes its reviews in order to examine those with the greatest potential impact on human health; (iii) FDA is hampered by the lack of a system that consistently tracks the receipt and review of submitted materials; (iv) FDA conducts limited monitoring and surveillance to identify violations that would not be identified through its review of submitted materials, for instance, discussions between doctors and sales representatives; (v) during calendar years 2003 through

2007, FDA issued 42 regulatory letters in response to off-label promotions requesting drug companies to stop dissemination of violative promotions.

**4. Mallinckrodt's false and misleading marketing of Acthar for a "mode of action" that is unknown, and for uses and doses that are not approved by the FDA.**

79. According to the "Pre-Decisional Agency Memo" issued September 27, 2010 by the DDMAC for Acthar, NDA 022432 ("**DDMAC Memo**"), the formulation of ACTH now known as H. P. Acthar Gel (Repository Injection), which is known generically as corticotropin, was originally approved by the FDA *prior to* the 1962 Kefauver-Harris Amendment to the Federal Food, Drug And Cosmetics Act of 1962 ("FDCA"), which introduced the requirement of "substantial evidence" of two adequate and well controlled studies. ***See DDMAC Memo attached hereto at Exhibit "B" hereto.***

80. In its 2010 assessment of Acthar, the DDMAC observed:

At the time of the original approval drug manufacturers only had to show the drug was safe for use in humans. The original data included case reports from a few physicians describing patients with conditions originally treated with Acthar powder that were transferred to treatment with Acthar Gel and gave dosing guidance for treatment of these individual conditions. A few patients had improvements in hematology data and improvement in symptoms (decreased diarrhea, improved appetite, sense of well-being, etc.) reported to support the efficacy of treatment.

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**These data would be grossly inadequate to support approval of a new drug or new indications by the Agency under current standards requiring evidence from adequate and well-controlled clinical trials.**

DDMAC Memo at 2-3 at Exhibit "B" (emphasis supplied).

81. Remarkably in 2017, Mallinckrodt falsely stated that when the FDA reviewed Acthar's label in 2010, it "determined there was sufficient scientific evidence and clinical evidence to support the 19 indications now in the current label." **Mallinckrodt Statement on**

**H.P. Acthar Gel (Repository Corticotropin Injection) Update, dated June 22, 2017, attached hereto as Exhibit “C” (“Mallinckrodt 2017 Statement”).** The Mallinckrodt 2017 Statement claimed to “[t]o address the false and misleading information about Mallinckrodt Pharmaceuticals and its product H.P. Acthar Gel,” when in point-of-fact, it did the opposite: it presented a demonstrably false and misleading picture about Acthar’s safety (including the increasing incidence of adverse events), efficacy and approval by the FDA.

82. In fact, directly contradicting Mallinckrodt’s false claims about the alleged “sufficiency of scientific evidence,” the Director of the Division of Neurology Products, Dr Russell Katz, wrote:

The sponsor [Mallinckrodt] had not conducted any trials of its own, and, in brief, we determined that the sponsor should attempt to obtain primary data for several trials published in the archival literature that, potentially, could provide substantial evidence of effectiveness for Acthar Gel for IS.

\* \* \*

The data that the sponsor has provided differ considerably from that typically submitted in an NDA. As noted earlier, **none of the studies were commissioned or conducted by the sponsor, and detailed protocols, and, in particular, detailed statistical plans for the analyses of these studies, did not exist.**

April 5, 2010 Memorandum from Russell Katz, M.D. at 1, 9 (available at [https://www.accessdata.fda.gov/drugsatfda\\_docs/nda/2010/022432Orig1s0900SumR.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/nda/2010/022432Orig1s0900SumR.pdf)) (emphasis supplied).

83. Mallinckrodt continued to press its false and misleading narrative about the FDA’s purported “approv[al] for 19 indications ... following a full label review by the Agency in 2010” into 2018, when Local 420 began to pay for Acthar. *See Mallinckrodt Statement, “Facts About H.P. Acthar Gel, H.P. Acthar Gel Value to Patients” dated June 29, 2018 attached hereto as Exhibit “D” (“Mallinckrodt 2018 Statement”).*



5. **Acthar's DESI review and narrowing of approved indications due to a lack of proven efficacy and safety.**

84. Despite published reports that Acthar was somehow “grandfathered” by the FDA, in truth Acthar was subjected to a Drug Efficacy Study Implementation (DESI) review in the early 1970s. The FDA has always required proof of safety and efficacy for the approval of prescription drugs.

85. At the time of the 1962 amendments to the FDCA, there were thousands of drugs on the market whose effectiveness was suspect or altogether unknown. The amendments thus required the FDA to *withdraw* prior approval of a drug if it found: “on the basis of new information before [it] with respect to such drug, evaluated together with the evidence available to [it] when the application was approved, that there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling thereof.” *FDCA, 21 U.S.C. § 355(e)*.

86. Acthar was thus subjected to a DESI review in 1971, and was **found to be effective only for a narrow subset of indicated uses**. The 1971 report titled “Corticotropin for Parenteral Use”, Federal Register, Vol. 36, No. 152 (Aug. 6, 1971) at 14509-14510, found Acthar “lacking substantial evidence of effectiveness” for its “recommended use” in over 30 of its originally approved indications. With respect to certain of the remaining indications, the FDA found Acthar “probably effective”; for others, the FDA found “these drugs are regarded as possibly effective for their labeled indications.” *Id.* at 14510.

87. In 1977, the FDA issued a “Follow Up Notice and Opportunity for Hearing”, Federal Register, Vol. 42, No. 40 (March 1, 1977) at 11891-11892, in which it reported:

[on] August 6, 1971, the [FDA] announced its conclusions that the drug products described below [including Acthar] are effective, probably effective, possibly effective, and lacking substantial evidence of



effectiveness for their various labeled indications. The notice provided an opportunity for a hearing for the indications concluded at the time to lack substantial evidence of effectiveness. **No data in support of any of the less-than-effective indications were submitted. All such indications are now reclassified to lacking substantial evidence of effectiveness. ...No person requested a hearing concerning them, and they are no longer allowable in the labeling.**

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**The drugs now lack substantial evidence of effectiveness for the indications evaluated as probably and possibly effective for the indications evaluated as probably and possibly effective in the August 6, 1971 notice.**

*Id.* (brackets added)(emphasis supplied).

88. As a result, Acthar was left with about 19 narrow indications. For instance, in the area of “rheumatic disorders”, the disease for which Acthar was prescribed for Local 420’s beneficiary, Acthar was approved only “as adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in ... rheumatoid arthritis”. *Id.* at 11892 (parenthetical in original).

89. All other indications had been “reclassified to lacking substantial evidence of effectiveness” by the FDA. Nevertheless, Mallinckrodt has continued to tout Acthar’s original approval in 1952 for “over 50 indications” in an effort to convince physicians, patients and TPPs that Acthar is widely approved to treat array of diseases, as opposed to just the 19 narrow indications for which it is actually approved. *See* listing of approved conditions below.

90. By the 1960s, Acthar was essentially a generic drug. Injectable ACTH medications faced a variety of competing products. *See Armour & Co. v. Wilson & Co.*, 274 F.2d at 145 (“Both Armour and Wilson manufacture and sell gelatin-ACTH preparations . . . . Gelatin-ACTH now constitutes more than 80% [o]f all forms of ACTH products sold by Armour and Wilson. Other companies . . . produce similar products”).

91. For the majority of the Acthar's drug lifespan, however, generic corticosteroids, such as prednisone, effectively treated the majority of the indications for which Acthar was approved. That factor tended to limit the market for Acthar to treating infantile spasms ("IS") which was originally an "off-label" indication. Consequently, because of the limited, off-label market for Acthar, by 2001, the drug was priced at \$40 per vial and accounted for less than a million dollars of revenue for Aventis, the then-owner.

92. Because prednisone is equally efficacious as Acthar, it has the same risks and benefits as Acthar, but at a far cheaper price. According to GoodRx.com, prednisone is available at leading retail pharmacies for little more than \$4 (with coupons), including Walmart, Target, CVS, Walgreens and Giant.

93. Despite this, Mallinckrodt has continually marketed Acthar as the new and improved prednisone, but without any support through head-to-head studies with prednisone. While prednisone has been proven to be safe and effective for the vast majority of indications on Acthar's label, there is no data to support Mallinckrodt's claims that Acthar is equally or more efficacious than prednisone, or other corticosteroids, so as to warrant even the same price as prednisone, let alone the exorbitant price of Acthar.

94. The same is true of Solu-Medrol (methylprednisone), a synthetic corticosteroid used to treat some of the same conditions for which Mallinckrodt promotes Acthar. Specifically, Solu-Medrol is given to people with multiple sclerosis ("MS") to shorten relapses. The cost of Solu-Medrol is around the same price as what Acthar used to cost, before Mallinckrodt acquired the product in 2001.

95. To try to deflect attention from the stark price differences between Acthar and generic prednisone, Mallinckrodt has engaged a small army of dedicated, highly-paid spokes-

doctors as KOLs to work with Mallinckrodt MSLs and its large sales force to promote sales of Acthar to the KOLs' peers. These KOLs work with Mallinckrodt and UBC to circumvent and bypass protections and controls imposed by TPPs to control and limit their expenditures on high-priced specialty drugs, like Acthar.

96. One major control utilized by payors is a "prior authorization" ("PA") process whereby a prescription for high-priced specialty medication like Acthar must be reviewed and authorized *before* the script written by the doctor is filled and charged to the TPP. However, Mallinckrodt and UBC have systematically circumvented such controls by their insistence that all patients and providers signing the blanket consents included on the Acthar Start Form at **Exhibit "A" hereto**, put in place in 2007 as part of the "new strategy". All such forms are faxed to UBC and processed through the "HUB" as described below, ensuring that unapproved uses and doses, like those prescribed to the beneficiaries of Local 420, IUOE Local 542, and other TPPs in the Class, are paid for at Mallinckrodt's inflated AWP.

**6. Acthar's approved label indications.**

97. As stated above, the FDA has approved Acthar for multiple, but limited, indications. These narrow indications, as set forth in the FDA-approved label, are:

- a. As monotherapy for the treatment of infantile spasms ("IS") in infants and children under two years of age;
- b. For the treatment of acute exacerbations of Multiple Sclerosis ("MS") in adults;
- c. As adjunctive therapy for short term administration (to tide the patient over an acute episode or exacerbation) in the following Rheumatic Disorders: Psoriatic arthritis, Rheumatoid arthritis, including juvenile rheumatoid arthritis (selected cases may require low-dose maintenance therapy), Ankylosing spondylitis (collectively, "RA");

- d. During an exacerbation or as maintenance therapy in selected cases of the following Collagen Diseases: systemic lupus, erythematosus, systemic dermatomyositis (polymyositis)(collectively, “SLE”);
- e. For the following Dermatologic Diseases: Severe erythema multiform and Stevens-Johnson syndrome;
- f. For serum sickness;
- g. For symptomatic sarcoidosis;
- h. To induce a diuresis or a remission of proteinuria in the nephrotic syndrome (“NS”) without uremia of the idiopathic type or that due to lupus erythematosus.

98. Despite these many, narrow indications, substantially all of Mallinckrodt’s sales have been generated from just five of these indications: (1) IS, (2) MS, (3) SLE, (4) NS, and (5) RA.

**7. Multiple Sclerosis (MS), Systemic Lupus Erythematosus (SLE), Nephrology Syndrome (NS) and Rheumatoid Arthritis (RA).**

**a. Multiple Sclerosis**

99. Multiple sclerosis (“MS”) is a central nervous system disease in which the body’s immune system attacks the body’s myelin nerve cell coating. MS can cause a variety of symptoms, which can increase in severity periodically.

100. MS “relapses,” “acute exacerbations,” or “flares” (collectively “MS exacerbations”) are temporary periods of increased disease activity in an MS patient, manifested by the worsening of existing MS symptoms or the onset of other MS symptoms. MS exacerbations are not a separate disease from MS.

101. The FDA has approved several medications for the long-term treatment of MS patients, including medications to slow the accumulation of physical disability from the disease or to decrease the frequency of acute exacerbations. These medications are sometimes referred

to as MS “disease modifying” drugs or therapies. Acthar is not a “disease modifying” drug or therapy for MS.

102. The FDA also has approved drugs for treatment of MS exacerbations, such as Acthar. A standard treatment for MS exacerbations includes administering methylprednisolone, a steroid, which can be administered intravenously (“IVMP”) or orally. One such treatment is Solu-Medrol. Both IVMP and oral methylprednisolone are available in several brand name or generic forms. The drugs are significantly less expensive than Acthar. Depending on the pharmacy from which it is obtained, generic methylprednisolone can be had for as little as \$34 per gram, without coupon.

#### **b. Systemic Lupus Erythematosus**

103. Systemic lupus erythematosus (“SLE”) is an autoimmune disease in which the body's immune system targets its own healthy cells. Lupus can damage the kidneys, brain, skin, joints, or other areas of the body.

104. SLE patients can experience “flares” or “exacerbations” (collectively “SLE exacerbations”), which are periods of increased disease activity and are characterized by worsening SLE symptoms.

105. SLE exacerbations are not a separate disease from SLE.

106. A standard treatment for SLE exacerbations includes the administration of steroids, which can be available in brand name or generic forms. The drugs are significantly less expensive than Acthar.

### **c. Nephrology Syndrome**

107. Nephrology syndrome (“NS”) is a kidney disease that causes one’s body to excrete too much protein in the urine. NS is usually caused by damage to the clusters of small blood vessels in one’s kidneys that filter waste and excess water from the blood.

108. A standard treatment for NS includes the administration of steroids, which can be available in brand name or general forms. The drugs are significantly less expensive than Acthar.

### **d. Rheumatoid Arthritis**

109. Rheumatoid arthritis (“RA”) is an inflammatory autoimmune disease in which the body's immune system targets itself, including the joints. RA patients can experience “flares” or “exacerbations” (collectively, “RA exacerbations”), which are periods of increased disease activity and are characterized by worsening RA symptoms.

110. RA exacerbations are not a separate disease from RA.

111. A standard treatment for RA exacerbations includes the administration of steroids, which can be available in brand name or general forms. The drugs are significantly less expensive than Acthar.

## **8. Dangers of Acthar for unapproved uses and doses**

112. Acthar is a dangerous drug with wide ranging and potentially life-threatening adverse effects. Thus, its FDA-approved label specifically warns that patients taking Acthar may suffer the following adverse effects:

- a. increased susceptibility to new infection and increased risk of exacerbation, dissemination or reactivation of latent infections, although signs and symptoms may be masked;
- b. adrenal insufficiency;

- c. Cushing's Syndrome;
- d. elevated blood pressure;
- e. masking of symptoms of other underlying diseases and disorders;
- f. gastrointestinal perforation and bleeding;
- g. behavioral and mood disturbances, including euphoria, insomnia, mood swings, personality changes, severe depression and psychosis;
- h. comorbid diseases, such that symptoms of diabetes and myasthenia gravis may be worsened;
- i. ophthalmic effects, such as cataracts, infections and glaucoma;
- j. loss of endogenous activity;
- k. enhanced hypothyroidism or liver cirrhosis for patients already suffering from these conditions'
- l. negative effects on pediatric growth and physical development;
- m. decrease in bone density; and
- n. potential fetal harm in patients who are pregnant, or may become pregnant.

113. Additionally, the FDA-approved label warns that patients taking immune suppressive doses of Acthar should not be administered live or attenuated vaccines.

114. In view of Acthar's unusual safety profile, the FDA took the additional, non-standard step when it approved Acthar for the treatment of IS in 2010 of also approving a Risk Evaluation and Mitigation Strategy (REMS) that requires Mallinckrodt to distribute an approved Medication Guide with each prescription, and also to submit REMS Assessments to the FDA at periodic intervals following approval of the REMS. The approved Medication Guide elaborates on the serious and significant side effects associated with Acthar.

115. As set forth below, the case of Patient A demonstrates how Defendants scheme directly impacted patient safety, contrary to the FDA-approved Acthar label.

## **B. THE ACTHAR “DISTRIBUTION SCHEME”**

### **1. Questcor acquires Acthar from Aventis.**

116. In 2001, Questcor acquired Acthar from Aventis Pharmaceutical Products, Inc. (“Aventis”) for only \$100,000, but in 2014 Mallinckrodt acquired Questcor for approximately \$5.9 billion.

117. In the July 27, 2001 Asset Purchase Agreement between Aventis and Questcor, Questcor acknowledged that there were risks in the transaction due to the limited approved indications for Acthar. Indeed, Questcor and Aventis held a meeting with FDA on February 7, 2001 in which such issues were discussed. Nevertheless, Questcor went through with the purchase.

118. Acthar’s value was limited because it was the “gold standard” for treating only one condition, infantile spasms (“IS”). IS is a serious condition in infants, but one with an annual patient population of less than 2,000 children per year. However, Acthar was not originally approved by the FDA to treat IS, further limiting its value. In 2010, the IS indication was approved by the FDA, and orphan drug status was granted.

119. Between 2001 – 2007, Acthar’s primary sales were for the treatment of IS, despite its off-label indication.

### **2. Sigma Tau’s Ownership and Control of Questcor, and the Launch of the “New Strategy”.**

120. In 2001, Questcor was floundering as a company until it got millions of dollars from Sigma Tau Finanziaria, an Italian drug conglomerate run by brothers Claudio and Paolo Cavazza, giving the Cavazzas and Sigma-Tau approximately 31% of the common stock outstanding as of March 15, 2002 and making them the largest shareholder in Questcor. Indeed,



in its 2001 10-K, Questcor admitted that “these shareholders can control the outcome of certain shareholder votes, including votes on election of directors, ... and other significant corporate transactions.”

121. In addition, the Cavazzas owned warrants to purchase another 2,559,494 shares of common stock, as well as a \$2.0 million 8% convertible debenture, giving them even greater control over Questcor and its decision-making.

122. According to Questcor’s public filings, the company reported the following:

In April 2001, we entered into a Stock and Warrant Purchase Agreement with Sigma-Tau Finance Holding S.A. (“Sigma-Tau”) pursuant to which Sigma-Tau purchased (i) an aggregate of 2,873,563 shares of common stock at a purchase price of \$0.52 per share, for an aggregate purchase price of \$1,500,000, and (ii) a warrant to purchase an additional 2,873,563 shares of common stock at a purchase price of \$0.52 per share. In May 2001, as required under the rules of AMEX, we sought and received shareholder approval to allow for full exercise of the warrant. In July 2001, Sigma-Tau assigned the warrant to Paolo Cavazza and Claudio Cavazza, the principal shareholders of Sigma-Tau, who exercised the warrant in full, purchasing 2,873,563 shares of common stock at a purchase price of \$0.52 per share, resulting in aggregate proceeds to us of \$1,500,000 (including the \$100,000 originally paid by Sigma-Tau to acquire the warrant).

In July 2001, concurrent with our agreement to acquire Acthar from Aventis, we entered into a Stock Purchase Agreement with Sigma-Tau pursuant to which Sigma-Tau purchased 5,279,034 shares of common stock at a purchase price of \$0.66 per share, for an aggregate purchase price of \$3,500,000.

In December 2001, we entered into a Promotion Agreement with VSL Pharmaceuticals, Inc., a private company owned in part by the principal shareholders of Sigma-Tau, to promote, sell and distribute the product VSL#3 in the U.S. In connection with this Promotion Agreement, we entered into two Stock and Warrant Purchase Agreements, one with Paolo Cavazza and one with Claudio Cavazza, to purchase (i) an aggregate of 640,000 shares of common stock for a purchase price of \$1.50 per share (representing a twenty percent premium to our market price for the five days prior to execution of the Purchase Agreements), for an aggregate purchase price of \$960,000, and (ii) warrants, at an aggregate purchase price of \$300,000, to purchase an additional 1,800,000 shares of common

stock at a purchase price of \$1.75 per share before December 1, 2003. We issued the common stock related to this transaction in February 2002. Additionally, in connection with this transaction, we entered into a standstill agreement with Sigma-Tau whereby Sigma-Tau and its affiliates agreed to limit purchases of common stock on the open market to no more than 2,000,000 shares through July 2003. Assuming Sigma-Tau exercises its warrants in full, they would own approximately 34% (including the 640,000 shares of common stock issued in February 2002) of our outstanding common stock as of December 31, 2001.

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On March 15, 2002, in two separate transactions, we issued \$4.0 million of 8% convertible debentures to an institutional investor and Sigma-Tau. We will pay interest on the debentures at a rate of 8% per annum on a quarterly basis. The debentures are convertible into shares of our common stock at a fixed conversion price of \$1.58 per share (subject to adjustment for stock splits and reclassifications). At the end of the term of the debenture, under certain circumstances, we have the option to repay the principal in stock and, under certain circumstances, we can also redeem the debenture for cash prior to maturity. The debentures mature on March 15, 2005. In conjunction with this transaction, we issued warrants to both the institutional investor and Sigma-Tau to acquire an aggregate of 1,518,988 shares of common stock at an exercise price of \$1.70 per share. Both warrants expire on March 15, 2006....

123. Importantly, a few years earlier, Claudio Cavazza had earned notoriety, and 1 ½ years of probation, for his role in a 1993 scandal in which he admitted paying kickbacks to health officials to get Sigma Tau products onto Italy's national drug formulary at increasingly higher prices. He also reportedly delivered bribes on behalf of other drug companies.

124. But Claudio's criminal record, a record of bribes to force payers to overpay for prescription drugs, did not stop Questcor from taking the Cavazzas' money and ceding effective control of the company to the Cavazza brothers in conjunction with Questcor's acquisition of Acthar.

125. Instead, Questcor allowed the Cavazzas to build their ownership stake in Questcor to more than 30%, giving them substantial control over Questcor's Board of Directors.

126. The Cavazzas used that control to install one of their own, Gregg LaPointe, to the Questcor Board of Directors.

127. In 2001, LaPointe was the Vice-President of Finance for Sigma Tau Pharmaceuticals, Inc. of Gaithersburg, Maryland (“Sigma-Tau Pharma”). Sigma Tau Pharma was the wholly-owned, U.S. subsidiary of Sigma-Tau. By 2003, LaPointe was the Chief Operating Officer (“COO”) of Sigma Tau Pharma. He was elevated to CEO in April 2007, in conjunction with his adoption of the below-described “new strategy” for Questcor’s sale of Acthar.

128. With the Cavazzas effectively in control, and now with LaPointe on the Questcor Board, the situation was ripe for fraud and abuse with Acthar, the likes of which have never been seen before, especially with a prescription drug of such limited therapeutic value.

**3. Mallinckrodt Adopts a "New Strategy" to Restrict Acthar Distribution and Aggressively Market Acthar for Unapproved Uses and Doses Through a Scheme of Kickbacks and Inducements**

129. Acthar is a specialty pharmaceutical distributed directly to patients, like the beneficiaries of Local 420 and IUOE Local 542 in this case.

130. For decades, Acthar was distributed to any doctor, hospital, wholesaler or specialty pharmacy who requested the drug to treat seriously ill patients. After Questcor acquired the rights to Acthar, it initially maintained that broad distribution network.

131. However, on July 2, 2007, Mallinckrodt restricted its distribution from three wholesalers, termed Wholesalers “A”, “B”, and “C” in its 2007 10-K, to just Express Scripts.

132. The goal of this “new strategy” was to lock patients into receiving Acthar through one distribution channel controlled by Mallinckrodt, and to ensure prescription distribution and

payment through one source, UBC. UBC is Mallinckrodt's self-described "HUB" of operations for Acthar. Mallinckrodt has maintained this exclusive arrangement with UBC since 2007.

133. However, the original officers and directors of Mallinckrodt did not agree with the "new strategy". Accordingly, two Directors on the Mallinckrodt Board engineered a coup to take over the company, to replace the CEO and to have the company adopt the new strategy.

134. Mallinckrodt's "new strategy" was the brainchild of Defendant Gregg LaPointe, a critical member of the Questcor Board of Directors installed by the largest shareholders, the Cavazzas. LaPointe also served as a member of the Corporate Council of the National Organization for Rare Diseases ("NORD"), which served as an important player in Mallinckrodt's and UBC's scheme to minimize resistance and pushback by patients and physicians to Acthar's higher prices by serving as a leading distributor of free Acthar supplied by Mallinckrodt to patients who could not afford to pay the newly established new high prices.

135. LaPointe convinced Steve Cartt, Questcor's Chief Operating Officer and Executive Vice-President in charge of sales and marketing of Acthar at the time, that the company should implement the "new strategy" for Acthar.

136. Cartt and LaPointe approached then-Questcor Board member Don Bailey to garner his support for the new strategy. Their "offline discussions did not sit well with Questcor's President and CEO at the time, James L. Fares.

137. In February 2005, James L. Fares was appointed President and CEO of Questcor by the Board of Directors. According to Albert Hanson, the Chairman of the Board, "the Board sought an accomplished pharmaceutical executive with substantial expertise in selling and marketing pharmaceutical products." Chairman Hanson further explained the selection of Feres as follows:

[T]he Board assessed each candidate's track record and capability to think creatively about Questcor's business. Such skills are critical in developing and executing a successful long-term strategy for a specialty pharmaceutical business. We looked for a talented executive who understood the specialty pharmaceutical market and had demonstrated the leadership skills necessary to create shareholder value. We believe that in Jim Fares we have found that executive. His successful track record in sales, marketing, business development, and general management, coupled with his energy and enthusiasm for pharmaceuticals, convinced us that we had found the right individual to lead Questcor.

138. Prior to joining Mallinckrodt, Feres held senior management positions at Merck, Athena Neurosciences and Elan Pharma. He founded and served as Sr. Vice President of Commercial Operations at Xcel Pharmaceuticals from 2001 – 2003. In his last position, he served as CEO and President of FGC Pharm/Novella Neurosciences. In sum, Feres was well qualified to lead a company like Mallinckrodt.

139. Feres resigned in May 2007, after taking the below-described 30% price increase for Acthar in February 2007. He was replaced by Don Bailey, whom the Board first appointed as Interim President, but then elevated to full-time President and CEO in conjunction with Mallinckrodt's adoption of the new strategy.

140. In sum, Bailey was not well qualified to lead a prescription drug company like Mallinckrodt. But he was willing to jettison responsible and ethical business practices in favor of the "new strategy", with unconscionable price increases [the Pricing Scheme] and an aggressive campaign of off label promotion fueled by misrepresentations and deception about Acthar's price, MOA, approved indications and doses, and value. For that, he was rewarded by being appointed the company CEO.

141. Mallinckrodt then signed contracts with Curascript and UBC in late June 2007 for the exclusive distribution of Acthar and exclusive operation of the HUB for ASAP.

142. Mallinckrodt and UBC then began to promote Acthar aggressively pursuant to the Pricing Scheme and Marketing Scheme detailed below. They did so to overcome resistance by providers, patients, and TPPs (like Local 420) to the high cost and limited value of Acthar.

143. Shortly thereafter, in July 2007, three Board members resigned, including the Chairman Albert Hanson.

144. In addition to CEO Feres, Mallinckrodt's Sr. Vice President of Strategic Planning and Communications, Eric Liebler, also quit. Liebler quit less than a year after being hired. He quit just three weeks after the "new strategy" was announced.

145. LaPointe also resigned within a week of the new strategy being launched, but not because he disagreed with the new strategy. Quite the contrary: his work on behalf of the Cavazzas was done. The Cavazzas had accomplished what they set out to do, engineering a coup at Questcor to take the company on an aggressive path centered around the new strategy and the three schemes detailed herein, the Distribution Scheme, the Pricing Scheme and the Marketing Scheme. Without LaPointe's installment on the Questcor Board, this would not have been possible.

146. These facts were confirmed by Questcor COO Steve Cartt on September 6, 2007, when he wrote to all senior staff at Questcor the following about LaPointe's departure:

Subject: Lapointe departure

Wanted to give you all a heads-up that Gregg LaPointe has left the Board of Directors (see attached link). This has been expected for some time actually, and is no cause for concern. Gregg joined the Board so that Sigma Tau could have some visibility on how Questcor was being run and the strategy going forward for the company. He actually as you can imagine ended up spending far more time on Questcor business over the last year than he ever imagined. Sigma Tau, our largest shareholder, is now comfortable with the company's path forward now, and is interested in having Gregg fully focused on Sigma Tau's own US business going forward, so the decision was made.

Also, in case you were wondering, Gregg has been a big supporter of the pricing strategy from the very beginning, so his departure was not the result of any disagreement with strategy. Quite the contrary actually.

Let me know if you have questions. Thanks, Steve.

147. It is believed and therefore averred that this mass exodus of leading executives and Board members was caused by Mallinckrodt's decision to adopt the "new strategy", with the Distribution Scheme, the Pricing Scheme and the Marketing Scheme as the hallmarks of an overarching scheme to raise Acthar prices, and overcome TPP resistance to high drug prices.

148. The decision to change the distribution, pricing and marketing strategies for Acthar was highly lucrative for all who supported it.

149. For instance, between 2006-2007, Don Bailey was permitted to purchase tens of thousands of shares of Questcor stock for \$1.67 per share. He also received warrants to buy tens of thousands of additional shares of stock at just \$0.44 per share. After the new strategy was pushed through, and the company started gouging patients and payers for Acthar, Bailey sold his shares, making tens of millions in profits.

150. Bailey's last warrant exercise and sale of Questcor stock took place in the summer of 2014, just prior to Mallinckrodt's purchase of Questcor. He exercised warrants to purchase 40,000 shares of common stock at \$5.12 (at a total cost of \$204,800). He then sold the same stock one month later at \$91.96 per share (at a total price of \$3,678,240). This was a profit of more than \$3.2 million in one month!

151. All told, Don Bailey earned tens of millions of dollars in just over 7 years through his insider stock sales alone, not counting his lucrative executive and Board member package of salary and benefits.



152. The self-described “orphan drug strategy” worked as follows: despite the fact that Acthar was an older drug, Mallinckrodt would “re-launch” Acthar with a new, limited distribution system and a substantially higher price, to make it appear as if Acthar were a new product being launched as the only product indicated for IS, an off-label indication at the time.

153. The IS market was a captive market involving a life-threatening disease afflicting infant children. Like other debilitating or life-threatening, orphan conditions, for which there was only one, sole-source drug treatment, IS presented Mallinckrodt with an opportunity to leverage its position against a particularly fragile, powerless patient population in an extremely narrow market.

154. As a result, Mallinckrodt predicted that the IS market would likely be able to absorb a much higher price with little resistance. In contrast, Mallinckrodt feared that the market for drug treatments of other disease states, such as the MS market, would not tolerate such a high price. Nevertheless, Mallinckrodt only viewed the anticipated resistance to higher prices by patients and payors as a challenge to be overcome.

155. Mallinckrodt and UBC overcame such challenge in several ways, as part of a new marketing and sales scheme, including the following:

- (i) knowingly disregarding federal laws and FDA regulations prohibiting off-label marketing and promotion;
- (ii) knowingly misrepresenting the purported efficacy, safety and value of Acthar for the treatment of unapproved conditions and unapproved doses in promotional and marketing material not submitted to, reviewed by, or approved by the FDA;
- (iii) failing to disclose and submit to the FDA all of their promotion, advertisements and marketing materials, as required by law;
- (iv) promoting the sale of Acthar for uses that were not proven to be safe or effective, as required by law;
- (v) promoting the sale of Acthar for doses that were not proven to be safe or



effective, as required by law;

(vi) willfully underreporting adverse events, as required by law;

(vii) utilizing improper, false and misleading comparative marketing tactics, such as comparing Acthar to prednisone, and including unsubstantiated superiority and value claims; and

(viii) improperly compensating healthcare professionals with free vials of Acthar, speaking and consultant fees and benefits, and other kickbacks as an inducement to induce them to promote and prescribed Acthar to their patients.

(ix) operating patient assistance programs as a means to secretly channel funds to third parties to pay for patient copay obligations, to remove patient complaints about the high costs of Acthar, and to force TPPs like Local 420 to pick up the balance of the Acthar bill.

156. The new pricing established by Mallinckrodt under the Pricing Scheme was only limited by what Mallinckrodt predicted that payors, like Local 420, would be willing to bear. This was because the Marketing Scheme adopted at the same time ensured that the promotional message delivered by UBC, as well as Mallinckrodt sales representatives and MSL's, was false, misleading and deceptive, and backed by unlawful kickbacks and inducements.

157. Mallinckrodt Executive Vice-President, Steve Cartt, admitted “[w]e did some market research,’ . . . [t]alking to physicians and others about pricing ‘gave us some comfort that the [new] strategy would work, and physicians would continue to use the drug, and payers would pay’ . . . . ‘The reality was better than we expected.’”<sup>4</sup>

#### **4. The Acthar Support & Access Program and the UBC “HUB”.**

158. One of the primary means by which Defendants carried out their unlawful scheme and conspiracy was through a program known as the “Acthar Support & Access Program” or “ASAP.” This program was structured to ensure that Mallinckrodt could ship its Acthar directly

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<sup>4</sup> Milt Freudenheim, *Benefit Managers Profit by Specialty Drug Rights*, New York Times, C1, April 19, 2008 (titled *The Middleman's Markup* in New York Print Ed.)(hereinafter, “*Freudenheim*”).

to patients, and then receive guaranteed payments directly from the TPPs who provide prescription drug coverage for their beneficiaries.

159. The ASAP was adopted by Mallinckrodt and UBC in 2007, as part of the “new strategy”. UBC’s predecessor became the exclusive operator of the ASAP program for Mallinckrodt.

160. Under the ASAP, all Acthar prescriptions are routed through UBC to patients, and all Acthar payments are coordinated by UBC to Mallinckrodt.

161. This process is generally laid out in the Acthar Start Form provided by Mallinckrodt (at Exhibit A hereto).

162. Once the patient (or their physician) seeks a prescription of Acthar, they are directed to UBC by Mallinckrodt’s sales representatives, MSLs or KOLs. They are then required to fill out and fax back to UBC the Acthar Start Form in order to obtain Acthar. There is no other way to get Acthar.

163. Upon receipt of the Acthar Start Form, UBC confirms the prescription by the provider and the associated specialty pharmacy, and then confirms the patient’s insurance coverage or other source of payment. UBC then arranges for the Acthar to be delivered directly to the patient by CuraScript.

164. Copies of the Acthar Start Form are attached to the Strunck & Pratta Complaint at Exhibit “H” and “I”. These Qui Tam Relators have confirmed that this is the process for Acthar.

165. The Acthar Start Form requires the patient and the physician to authorize the prescription as “medically necessary”, and to payment as appropriate before Mallinckrodt will ship the Acthar to the patient. Mallinckrodt have used a version of the Acthar Start Form for all

year from 2007 through the present. For this entire time period, such forms are required to be faxed to UBC, via the used of the wires.

166. The Acthar Start Form consists of 3 sections: (1) a section requiring signature by the “HCP” (or health care professional); (2) a patient authorization requiring signature by the “patient or legal representative”; and (3) information concerning Acthar indications and usage. The required signature of the patient authorizes “Mallinckrodt and its agents” to do a number of things in relation to the prescription and distribution of Acthar. It further authorizes Mallinckrodt and its agents, “including Mallinckrodt reimbursement support personnel and United BioSource Corporation (“UBC”) or any other operator of the Acthar Support Access Program on behalf of Mallinckrodt (collectively, ‘Designated Parties’)” to provide Acthar and receive payment, among other things.

167. Specifically, the patient authorizes Mallinckrodt and UBC, its “Designated operator”, “to provide certain services to [the patient], including reimbursement and coverage support, patient assistance and access programs, medication shipment tracking, and home injecting training.” In other words, the patient directly authorizes UBC, as Mallinckrodt’s agent, to ship Acthar directly to them, and to receive payment from both the patient (for the co-pay) and the TPP prior to obtaining the medication.

##### **5. Direct Injury of Plaintiff and the Class.**

168. By the above-stated arrangements, Acthar product flows from Mallinckrodt to the patient, while the money flows from the patient and payor back to Mallinckrodt.

169. Mallinckrodt only “consigns” the Acthar to CuraScript, meaning that Mallinckrodt remains at risk for the sale of the product until it is shipped. Mallinckrodt maintains all right, title and interest to the Acthar until it is approved for delivery by UBC to the

patient and payment is assured by the TPP. Both possession and title pass to Acthar pass from Mallinckrodt to the patient and TPP, only after they both agree to pay for it via the Acthar Start Form and UBC's sign-off. UBC's role is to ensure that Mallinckrodt's "risk" is minimal because it will not authorize shipment until payment by the TPP is confirmed. At no time is either CuraScript or UBC at risk for the Acthar sold by Mallinckrodt.

170. In this way, TPPs like Local 420 and IUOE Local 542, along with other similarly situated members of the Class, are directly harmed by the conduct of the Defendants, because their beneficiaries receive the Acthar directly from Mallinckrodt, via its designated consignees, at their homes to be self-injected, and they make their co-payments, along with the TPPs, directly back to Mallinckrodt through this same arrangement.

171. This is a distinguishing feature of specialty drugs in general, from other brand name and generic drugs available at retail pharmacies, who received the drugs from wholesalers, who directly contract with drug manufacturers. Here, Mallinckrodt and UBC removed all the middlemen. There are no wholesalers or retailers between the patients and TPPs and the Defendants.

172. Further, Plaintiff and TPP members of the Class have paid the inflated AWP directly set and charged by Defendants. As a result, their injury is both cognizable – economic injury from a price overcharge – and direct – paying the price set and charged by the Defendants sued. The Class does not include any other potential payors who may have paid some other price than the inflated AWP for Acthar.

173. Mallinckrodt and UBC also uniquely interact directly with TPPs and their beneficiaries in this case to ensure their scheme is successful. Beyond direct consultation, they provide "Home Injection Training Services" or "HITS", by which Mallinckrodt pays to have a

nurse visit the patient to teach them how to self-inject the Acthar. UBC arranges for HITS, and tracks all such interactions through a database maintained for Mallinckrodt. All bills for such HITS are paid by Mallinckrodt, who is happy to provide free injection training to remove any potential obstacle to a patient taking Acthar.

174. The Acthar Start Form (Exhibit “A” hereto), by which all Acthar is prescribed, has section for the provider to request HITS for the patient.

175. These direct interactions between the Defendants and the Class give Plaintiff and the Class standing to sue on all counts. At a minimum, they raise serious fact questions about the uniqueness of Defendants’ scheme to allow this case to proceed to discovery.

### C. THE ACTHAR “PRICING SCHEME”

#### 1. **Defendants raise the AWP for Acthar, and charge such prices to TPPs, without regard for the lack of proven safety, efficacy or value of the drug to treat the diseases for which they market and sell Acthar.**

176. Mallinckrodt acquired the rights to Acthar from Aventis in July 2001.

177. At the time of its acquisition, the end payor price of a vial of Acthar charged to TPPs, like the Plaintiff, was approximately \$40.00.

178. After acquisition, Mallinckrodt raised the per-vial price substantially. By September 2001, Mallinckrodt raised the list price for Acthar, or the wholesale acquisition cost (“WAC”), to \$748.16. It raised the end payor price, or the average wholesale price (“AWP”), to \$935.20.

179. Like other brand name, injectable drug manufacturers, Mallinckrodt adopted a 25% markup factor for its AWP for Acthar. In other words, once Mallinckrodt sets a new WAC, the AWP is calculated at 25% above the new WAC.

180. From 2001 until Mallinckrodt executed its new strategy in 2007, the Acthar WAC grew from \$748.16 to \$1,650.23, while the AWP grew from \$935.20 to \$2,062.79 (25% higher than the WAC).

181. The below table reflects the WAC and AWP price changes (and the percentage increase) as implemented by Mallinckrodt from 2001 through February 2007, and as charged by UBC:

DATE	WAC	AWP	% INCREASE
Sept. 21, 2001	\$748.16	\$935.20	-
June 24, 2002	\$782.60	\$978.25	4.6
April 1, 2003	\$859.20	\$1,074.00	9.787
March 1, 2004	\$902.00	\$1,127.50	4.98
January 1, 2005	\$988.00	\$1,235.00	9.53
April 1, 2005	\$1,037.20	\$1,296.50	4.98
January 1, 2006	\$1,120.40	\$1,400.50	8.0
October 1, 2006	\$1,232.44	\$1,540.55	10.0
December 21, 2006	\$1,269.41	\$1,586.76	3.0
February 2, 2007	\$1,650.23	\$2,062.79	30.0

182. The double-digit price increase in 2005 and 2006 were not enough, nor as the 30% price increase in February 2007. Mallinckrodt's greed required more.

183. When Mallinckrodt implemented its new strategy with UBC on August 27, 2007, they raised the WAC for Acthar from \$1,650.23 to \$23,269.00. They also raised the AWP for Acthar from \$2,062.79 to a staggering \$29,086.25 – representing a 1,310% increase in the span of a month, and a 72,615% increase from the time Mallinckrodt first acquired the drug.

184. Until Mallinckrodt obtained FDA approval for the IS indication in 2010, the price of Acthar remained relatively stable. However, in 2011, Mallinckrodt increased the price of Acthar three times: by 5% on January 3, 2011, by another 5% on June 1, 2011, and then by 6.5% on December 27, 2011. These three price increases totaled a staggering 16.5% in one year. As of 2012, Acthar's end payor price/AWP stood at \$34,150.00.

185. But Mallinckrodt and UBC were wary of TPP's increasing concerns about Acthar's price and lack of proven value for the various indications being promoted. A poignant example is the attempted price increase in September of 2012.

186. In September 2012, Mallinckrodt desired to take another 5% price increase. The decision to raise the Acthar price was made by Questcor's COO Steve Cartt in early September.

187. However, on September 19, 2012, health insurer Aetna, announced that it would cut back reimbursements for Acthar, due in part to the lack of evidence of Acthar efficacy for various disease states.

188. Questcor's stock plummeted 56% the same day as the Aetna announcement. Within a week, Questcor's stock had fallen another 37%.

189. Mallinckrodt scrambled to place the intended price increase "on hold for now", due to the Aetna situation. It so advised Curascript and UBC, which both agreed.

190. This price increase was later taken by the Defendants on June 7, 2013, when the Acthar WAC was increased 5% to \$30,120.00 and the Acthar AWP was increased 5% to \$37,650.

191. In 2014, Defendants resumed their aggressive price increase strategy, just prior to Mallinckrodt plc's \$5.9 billion acquisition of Questcor. But they continued to conceal the truth, lying to the public about the real reasons for the exorbitant price increases.

192. On January 16, 2014, the Acthar WAC and AWP were raised 5%, to \$31,626 and \$39,532.50, respectively.

193. Prior to Questcor's acquisition by Mallinckrodt plc in 2014, Questcor had planned an additional 5% increase for Acthar in December 2014. This would have meant a total percentage increase of 10% for the year.

194. However, after the acquisition, Mallinckrodt raised the planned increase to 8.9%, or 13.5% for the year.

195. In the interim, the Executive Committee (“EC”) of Mallinckrodt met. The EC consists of the senior management of Mallinckrodt, including President and CEO Mark Trudeau and Executive Vice President and Chief Commercial Officer Hugh O’Neill.

196. COO O’Neill raised the matter of the 8.9% price increase with the EC on Friday December 12, 2014, and it was decided by the Mallinckrodt leadership team to “change[] the magnitude” of the pricing action, reducing the proposed increase from 8.9% to 2%. The EC did this in order to take advantage of an “opportunity for breakthrough pricing strategies” in the future.

197. It is believed and therefore averred that such pricing opportunity was presented by Questcor’s prior acquisition of Synacthen, a synthetic version of ACTH.

198. Questcor had completed its acquisition of Synacthen in 2013.

199. As a result of such Synacthen acquisition, Mallinckrodt was confident that reducing the planned 8.9% Acthar price increase in late 2014 to little more than the consumer price index [which stood at about 1.7% in 2014] -- causing a \$26 million shortfall in the forecasted revenues [based on the 5% increase that was “baked in” for December] -- would not negatively affect the company moving forward. This decision, while ostensibly made against Mallinckrodt’s economic self-interest in the short term, was made to further enhance their profits in the long run.

200. Accordingly, with the direct input and hands-on decision-making by President and CEO Trudeau, Mallinckrodt reduced its December 2014 Acthar price increase to 2%. This



led to a WAC increase to \$32,260.00 and an AWP increase to \$40,325.00, respectively, on December 16, 2014.

201. Under Mallinckrodt plc's stewardship, the AWP of Acthar has continued to rise in to well above \$40,000 in 2018, when Local 420 began paying for it, despite Mallinckrodt's misrepresentations about Acthar's price.

202. In 2018, Mallinckrodt's CEO, Mark Trudeau, deliberately lied to the public in a press release. He willfully misrepresented that "[t]he current 'list price' per vial for the drug is \$36,382, not the higher numbers which have appeared in various reports, and Mallinckrodt discounts this list price to both public and private payers." *See* Mallinckrodt 2018 Statement at Exhibit "D" hereto. This statement was false, misleading and deceptive.

203. The price paid by "private payers", like Local 420 and the Class of TPPs in this case, is the AWP. As set forth above, that price has been in excess of \$40,000 since 2014. Mallinckrodt does not "discount" that price to Local 420, or any other TPP, as claimed.

204. If Mr. Trudeau was actually representing that the WAC for Acthar was \$36,382 as of June 2018, which is not the price paid by "private payers" like Local 420, then the AWP paid by private payers would have been actually a staggering \$45,477.50, based on the historical 25% markup Mallinckrodt has employed for its Acthar AWPs since the inception of its ownership in 2001.

205. Since the acquisition of Acthar in 2001, the end payor price of Acthar has grown over 100,000% reflecting the precipitous rise in the value of the Acthar assets from \$100,000 in 2001 to \$5.9 billion in 2014 – a 5,899,900% increase in value. Mallinckrodt has continued to deceive payors like Local 420 and the TPP Class about the actual prices of Acthar, and the reasons for its many staggering price increases.

206. In fact, in direct response to a lawsuit filed against Mallinckrodt in April 2017 by the City of Rockford, Illinois, Mallinckrodt issued a public statement, claiming to “set the record straight” about Acthar pricing and other issues. *See* Mallinckrodt 2018 Statement at Exhibit “D” hereto. This press release is replete with misrepresentations and deliberate falsehoods that only continues to deceive Local 420 and the Class about Acthar pricing and the actual reasons for the high Acthar prices.

207. The 2018 press release was issued by the company CEO Mark Trudeau who falsely, misleadingly and deceptively claimed that the “price of H.P. Acthar Gel today is \$38,892, before discounts provided to payers.” *Id.*

208. However, when Local 420 paid for Acthar in 2018, the Acthar AWP was well over \$40,000.00. In fact, the AWP for Acthar had been raised by Mallinckrodt to \$40,325.00 on December 16, 2014, 4 years before Trudeau willfully made his materially false statement about Acthar pricing.

209. Today, the price of Acthar stands at over \$43,000.

210. Mallinckrodt has conspired and agreed with UBC, and others, to conduct a fraudulent scheme and conspiracy to deliberately inflate the AWP for Acthar, to maintain such high AWP for Acthar in the face of complaints by patients and TPPs, like Local 420, to communicate such inflated prices, and to circumvent patient and payor concerns about Acthar’s high prices through the Distribution and Marketing Schemes alleged herein. As Defendants well know, the AWP is used by both government and private assistance programs for prescription drug reimbursement.

211. Government and private assistance programs, like those of Local 420 and the Class, have used the AWP's published in pharmaceutical industry publications, such as the Red Book and Medispan, for years as a basis for reimbursement, in whole or in part.

212. These publications set forth the false AWP's for Acthar, as reported with each price change by Mallinckrodt. In periodically announcing the AWP's for Acthar, the publications simply published the prices supplied to them by Mallinckrodt. Mallinckrodt knew that it could, and did directly, control and raise the AWP for Acthar at any time simply by forwarding to the pricing compendia a new and higher AWP.

213. This Pricing Scheme allowed Mallinckrodt to control, in conjunction with its Distribution and Marketing Schemes, its profit levels, and the profits of its HUB, UBC, by the direct manipulation and reporting of the Acthar AWP.

214. Years before Mallinckrodt and UBC engaged in their Pricing Scheme to manipulate the Acthar AWP's to increase their profits, in 2003, the Office of Inspector General ("OIG") admonished, "[i]f a pharmaceutical manufacturer purposefully manipulates the AWP to increase its customers' profits by increasing the amount the federal health care programs reimburse its customers, the anti-kickback statute is implicated." In re Pharm. Ind. Average Wholesale Price Litig., 491 F.Supp. 2d 20, 39-44 (D. Mass. 2007). Ironically, this published decision appeared the same month in 2007 that Mallinckrodt and UBC signed their first of many conspiratorial agreements to manipulate and communicate the AWP for Acthar.

215. Plaintiff is not alone in its charge of deceptive conduct against Mallinckrodt. In April 2015, Mallinckrodt settled a securities fraud class action brought by its investors against the company in January 2013 in the United States District Court for the Central District of California for the sum of \$38 million. The securities lawsuit charged the company with, inter

alia, “issu(ing) false and misleading statements about the effectiveness of, and prospects for, Questcor’s sole product, Acthar.” The court denied in part the Defendants’ motions to dismiss, allowing certain claims to proceed. The court then granted class certification in November 2014.

216. Following the settlement, Mallinckrodt’s CEO Mark Trudeau suggested to investors on October 6, 2015 that drug prices “should be reflective of the value that you deliver to the marketplace.”

217. However, following this settlement, and the filing of the Rockford lawsuit, leading executives at PBM Express Scripts (which owned UBC) conceded that Acthar is not worth what Mallinckrodt is charging for it, and what TPPs like Local 420 and IUOE Local 542 have been paying for it, especially for the treatment of MS, NS and RA. Despite this, neither Mallinckrodt nor UBC have changed their ways.

## **2. The Views of Express Scripts’ Senior Management On the Lack of Acthar “Value” for the Prices Charged.**

218. When Mallinckrodt chose to increase the price of this 50-plus year-old medication, the leading PBM, Express Scripts, did not push back. This likely due to its ownership of Curascript and UBC, which were both subsidiaries of Express Scripts at the time.

219. However, when confronted about the 2007 price increase in later years, Express Scripts’ Chief Medical Officer Steve Miller stated that “[t]he increase was a manufacturing decision. I can’t comment on it.”<sup>5</sup>

220. On May 19, 2017, just weeks after Mallinckrodt was sued by the City of Rockford in early April 2017 for, inter alia, price fixing, Express Scripts senior officers made comments about the “somewhat controversial” drug Acthar on a private investor conference call hosted by

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<sup>5</sup> *Freudenheim, supra*.

Citi.6 The Citi interviewer stated, “it’s been in the news as – given the pricing around the drug over the past – I don’t know – 12 months at least,” and then asked for “any thoughts around ... how that can be managed and how you see cost of the playing out?” Citi Transcript at 12.

221. In response, Express Scripts’ Senior Vice President, Supply Chain and Specialty Pharma, Everett Neville stated:

I don’t think [Acthar is] a very great [drug] – ***it’s a pretty poor drug with a very limited need*** and certainly [Express Scripts Chief Medical Officer, Dr.] Steve [Miller] could comment. He’s a doctor and I’m just a really bad pharmacist.

...[Y]ou know, and Steve, you could chime in here too, but I think Steve and I both would agree, and ***I think everybody in our company would agree, that the product is vastly overpriced for the value. We don’t set the price.*** We’ve told [Mallinckrodt] that. I personally told [Mallinckrodt’s] management team that their drug is hugely overpriced. I know Steve has as well.

*Citi Transcript at 12* (emphasis added) (brackets added).

222. Dr. Miller stated that he was in “100% agreement with [Mr.](Everett).” Citi Transcript at 12 (brackets added). He added, “[i]f you look at the data, the indications for the drug are really – while it had, in the compendium, it’s listed under a lot of indications, its real use should be very, very limited. It’s an old drug. There’s better products in the marketplace...”. Citi Transcript at 12-13.

223. One of the areas where Acthar should be limited is the treatment of rheumatic disorders, like the condition suffered by the beneficiary of Local 420.

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<sup>6</sup> See Conference Call Transcript of call hosted by the Citigroup Healthcare Team on May 19, 2017 at 11:00a.m. est, with Dr. Steve Miller, Chief Medical Officer from Express Scripts, and Mr. Everett Neville, Senior Vice President of Supply Chain and Specialty (“***Citi Transcript***

224. Indeed, in December 21, 2017, Express Scripts provided an updated “Prior Authorization Policy” for Acthar, effective January 2018 (hereinafter “2018 Prior Authorization Policy”).

225. The 2018 Prior Authorization Policy admitted that Acthar “may be used for ... rheumatic disorders as an adjunctive therapy for short-term administration for an acute episode or exacerbation (in psoriatic arthritis, rheumatoid arthritis, juvenile rheumatoid arthritis [selected cases may require low-dose maintenance therapy]...”.

226. The adult beneficiary of Local 420 was prescribed Acthar for a rheumatic disorder, but not for an RA exacerbation and not in low-dose form, as required.

**3. Mallinckrodt Acquires Acthar from Aventis at a Low Price Reflective of its Lack of Market Value.**

227. In 2001, Mallinckrodt, then Questcor, acquired Acthar from Aventis Pharmaceutical Products, Inc. (“Aventis”) for only \$100,000. This low price was reflective of the lack of market value for Acthar for the treatment of disease.

228. But in 2014, seven years after Questcor embarked on its “new strategy” for Acthar, Mallinckrodt acquired Questcor for approximately \$5.9 billion.

229. In the July 27, 2001 Asset Purchase Agreement between Aventis and Questcor, Questcor acknowledged that there were risks in the transaction due to the limited approved indications for Acthar. Indeed, Questcor and Aventis held a meeting with FDA on February 7, 2001 in which such issues were discussed. Nevertheless, Questcor went through with the purchase.

230. Acthar’s value was limited because it was the “gold standard” for treating only one condition, IS. IS is a serious condition in infants, but one with an annual patient population of less than 2,000 children per year. However, Acthar was not originally approved by the FDA to

treat IS, further limiting its value. As described above, the IS indication was not approved by the FDA until 2010. Between 2001 and 2010, IS was an *off-label indication* which Mallinckrodt actively marketed.

231. Between 2001 and 2007, Acthar's primary sales were for the treatment of IS, despite its off-label indication.

232. Consequently, because Mallinckrodt's primary business concerned the off-label marketing and sales of Acthar for IS, it is not surprising that it sought to expand upon such business model in other off label areas, once the IS indication was approved.

233. After the "new strategy" was adopted, Mallinckrodt expanded its marketing for other unapproved uses and doses in MS, NS, SLE and RA. As a result, sales expanded exponentially in these areas, expanding the profits of the company, all due to Mallinckrodt's company-wide campaign of off label promotion.

234. It was only because of the profits achieved in the areas other than IS that Questcor was deemed worth nearly \$6 billion to Mallinckrodt. Consequently, Mallinckrodt has continued to advance the distribution, pricing, marketing and sales schemes initiated by Questcor. These are not "legacy" matters, as Mallinckrodt has falsely claimed. Instead, they have been engrained in Mallinckrodt's business and corporate culture since the early 2000s.

235. For that reason, Local 420 and the Class seek declaratory and injunctive relief against Mallinckrodt to put an end to the ongoing schemes for the benefit and future protection of patients and private TPPs, regardless of whether the federal government chooses to settle with Mallinckrodt. The putative Class described below expressly excludes government payors who have settled with Mallinckrodt.

**D. THE ACTHAR “MARKETING SCHEME”.**

236. The Marketing Scheme in this case is identical to the scheme alleged in the Strunck & Pratta and Clark Complaints, and as amended in the U.S. Complaint in Intervention all filed and pending in this Court. The only difference is the affected class of plaintiffs – all private payors as opposed to the government payors in the government’s case.

237. To duplicate those factual averments would exponentially and unnecessarily grow the length of this already lengthy Complaint.

238. Nevertheless, Local 420 summarizes those averments herein to make clear that it and the Class of TPPs it seeks to represent suffered harm as a result such Marketing Scheme.

**1. As Part of its “New Strategy”, Mallinckrodt Creates a Team of Highly-Trained “Medical Sciences Liaisons” to Promote the Sale of Acthar at High Prices Through a Campaign of Misrepresentations and Deception in Conjunction with KOLs.**

239. As part of the new strategy in 2007, Mallinckrodt created a new position within the company: “Medical Science Liaison” or “MSL” were highly trained sales employees who were deployed to speak directly to doctors about the safety and efficacy of Acthar for unapproved uses and doses.

240. Mallinckrodt also employed MSLs to provide periodic training to employees of UBC.

241. Such training included information about Acthar’s approval uses and doses, as well as its purported safety and efficacy for unapproved uses and doses based upon Mallinckrodt-sponsored “open label” clinical studies, usually conducted by Mallinckrodt-paid KOLs.

242. In the Strunck & Pratta Complaint, they detail the important role the new MSLs played in the Mallinckrodt and UBC schemes alleged. Specifically, the allege:



Another tactic employed by Questcor to promote H.P. Acthar Gel off-label is to use its Medical Science Liaisons (“MSLs”) as an end-run around sales representatives’ duty to lawfully promote the drug. Questcor’s use of MSLs in this manner is a way for the company to make the unlawful promotional activities for H.P. Acthar Gel appear lawful. *See e.g.* 21 C.F.R. 99.101. et seq.

Medical Science Liaisons are supposed to talk with physicians only about science-to-science issues, and only when those discussions are initiated by the physician. Their primary role is to engage in non-promotional medical activities, and they are not supposed to engage in product promotion. Thus, a sales representative is not permitted to use an MSL as a conduit through which to initiate and pursue off-label promotion activities with physicians.

The law notwithstanding, Questcor erects no wall between its medical and sales staffs, and actively encourages its MSLs to probatively participate in promotional activities. Medical Science Liaisons routinely accompany Questcor sales representatives on their sales calls.

Questcor encourages its sales representatives to probatively partner with MSLs to increase H.P. Acthar Sales growth. Commonly, the sales representative will initiate an off-label discussion, and then the MSL will complete the discussion. On other occasions, sales representatives ask their MSL colleagues to contact physicians who are reluctant to prescribe H.P. Acthar Gel for off-label uses in order to attempt to overcome that reluctance whether or not the physician initiated the off-label discussion or requested further information. Again, Questcor ignores that MSLs are not permitted to engage in promotional activities.

Strunck & Pratta Complaint at ¶¶ 142-145.

243. The Relators then proceed to explain the critical role of these MSLs in promoting the off-label use of Acthar, especially for the unapproved, in effective and harmful 5-day dose prescribed to MS patients, like the patients of IUOE Local 542 described below. The specifically allege as follows:

#### **Five Day Course of Treatment Was Ineffective and Harmful to Patients**

Many physicians have rightfully rejected Questcor’s efforts because the 5-day protocol is not supported by any credible evidence, and because experimenting with it cannot be justified in light of its cost and potential for patient harm. However, many physicians have been persuaded to

switch from Solu-Medrol to a 5-day course of treatment with H.P. Acthar Gel – in large measure due to the valuable inducements provide to them by Questcor, as described herein.

In Relator Strunck's experience, approximately half the doctors he persuaded to prescribe H.P. Acthar Gel for a five-day course of treatment had to order repeat prescriptions in as few as two to three months due to patient relapse, even though patients treated with Solu-Medrol typically relapse only after twelve to eighteen months. Relator Strunck knows this issue was widespread, because it was regularly was [sic] discussed during regional sales team conference calls. In Relator Pratta's experience, she experienced the same reactions from patients who doctors use the five day [sic] course of treatment.

Questcor's decision to promote H.P. Acthar Gel only for a five-day course of treatment came at the detriment of patients and patient safety. The issue was routinely discussed during regional sales calls and national sales meeting, Questcor knew that although a typical patient treated with Solu-Medrol for five days would relapse in twelve to eighteen months, and that a typical patient treated with H.P. Acthar Gel would relapse in as few as two to three months.

Thus, the cost to treat a typical patient with Solu-Medrol would be less than \$5,000 over a five-year period (approximately four treatment cycles), but the cost to treat the same patient with H.P. Acthar Gel would be almost \$700,000 (approximately 30 treatment cycles). As an example, at the Regional Sales Meetings on March 7<sup>th</sup>-8<sup>th</sup> in 2013, held in New Brunswick, New Jersey Blainy Creasy, the region's new Medical Science Liaison (MSL) gave a scientific talk about Acthar and its new mechanism of action (MOA) and how they intend to position it in the physician's offices. Stacy Clancy said that *"even though we sell 5 day, the docs are finding out that it is not working and some patients need another vial."*

Plainly, promoting a five-day course of treatment with H.P. Acthar Gel inured to the patient's financial detriment and, more importantly, to the detriment of the patient's health and well-being. Questcor promoted the five-day treatment cycle in order to get both the physician and the patient "hooked" on the substantially more expensive H.P. Acthar Gel in lieu of Solu medrol [sic].

Strunck & Pratta Complaint at ¶¶ 146-150.

**2. Mallinckrodt Uses KOLs to Create Biased Clinical Data to Deceive Patients and TPPs, and to Cultivate High Acthar Prescribers as “Spokes-Doctors”.**

244. In view of the extremely limited clinical data that existed at the time of Acthar’s approval in 1952, and since that time, Mallinckrodt has been forced to try to create data to support its false and misleading marketing effort about Acthar’s “value” to treat disease beyond the narrow indications on its label.

245. Mallinckrodt cultivated so-called “Key Opinion Leaders” or “KOL’s” create such data, and then disseminated such data to other doctors through their highly-compensated spokes-doctors.

246. As ProPublica has reported, and as demonstrated below by a few examples, dozens of high prescribers of Acthar have been cultivated as spokes-doctors and paid tens of thousands of dollars for their work on behalf of Mallinckrodt in this regard.

247. These KOLs are paid by Mallinckrodt to cultivate a narrow group of high prescribers of Acthar, some of whom are also engaged by Mallinckrodt to generate clinical data based on their own patient populations to support Acthar’s off-label uses and doses, without FDA oversight, input or scrutiny. The company then widely disseminates the results of such anecdotal studies as part of its vast marketing campaign to convince doctors that Acthar is safe and effective for unapproved uses.

248. As similarly alleged in the opioid litigation, in which Mallinckrodt has been sued as a defendant in MDL 2804 (pending in an Ohio Federal District Court) and in state courts throughout the country, including Pennsylvania, Mallinckrodt cultivated a select circle of doctors who were chosen and sponsored for their pro-Acthar messages in order to create “the grave misperception science and legitimate medical professionals favored the wider and broader use”

of Acthar. These KOLs were used to present the appearance that unbiased and reliable medical research supporting the broad use of Acthar for neurology, nephrology and rheumatology had been conducted and was being reported on by independent professionals. *See In re: National Prescription Opiate Litigation*, Case No. 1:17-md-02804-DAP, N.D. Ohio, Doc. No. 1025 (Report and Recommendation dated October 5, 2018) at 6-7.

249. The publications of many of these physicians, including those of Dr. James James A. Tumlin of Tennessee described below, were funded by Mallinckrodt as they supported the position that Acthar for broad use in neurology, nephrology and rheumatology was appropriate, all the while knowing these statements were false, misleading and deceptive.

250. Mallinckrodt utilized KOLs, like Dr. Tumlin, to develop “open label” clinical data to support Mallinckrodt’s promotion of Acthar for new indications in nephrology, neurology and rheumatology.

251. “Open label” clinical trials, unlike the FDA-approved trials described above, do not attempt to disguise the drug being studied, meaning that no standard treatment or placebo is utilized. This leans towards bias, as both the patient and the physician are aware of which groups are receiving what type of treatment. The results are thus unreliable.

252. In NS, for instance, Mallinckrodt was aware as early as 2009 that doctors were nearly unanimous in their expression of a need for clinical data to support the efficiency and safety of Acthar in NS, as well as the need for clarification on the appropriate dosing regimen. Working with KOLs who expressed interest in generating such data became a major focus for Mallinckrodt MSLs in 2009 and beyond.

**3. JAMA Study of Mallinckrodt KOLs, and Connection Between Kickbacks Payments and Higher Acthar Prescriptions.**

253. In June of 2018, a team of researchers and concerned clinicians used Medicare and Medicaid data to investigate the frequency of use and overall expense of Acthar. To characterize payments from Mallinckrodt to physicians who prescribe Acthar, these researchers and clinicians conducted a cross-sectional analysis of data from CMS, including the Medicare Part D Public Use Files. Focusing on 2015, the researchers used the database to identify physicians, and their specialties, who prescribed Acthar more than 10 times that year, characterizing them as “frequent prescribers.”

254. Their study, published in JAMA Network Open, found that in 2015 only 300 providers wrote more than 10 prescriptions for Acthar. Of those 300 prescribing providers of Acthar, 235 of them were rheumatologists, neurologists, or nephrologists.

255. Further, among those 235 rheumatologists, nephrologists and neurologists who issued more than 10 prescriptions for Acthar in 2015, 88% (207/235) received payments from Mallinckrodt – with more than 20% of those frequent prescribers receiving more than \$10,000 – despite Acthar’s considerable cost and the dearth of evidence to support its use.

256. Some physicians prescribing Acthar were paid as much as \$56,000-\$138,000 by Mallinckrodt for activities related to Acthar, making such payments equivalent to the salary of full-time employees of Mallinckrodt.

257. Indeed, as noted by one of the researchers and clinicians in the JAMA study, Dr. Daniel M. Hartung, “[e]xpensive therapies with uncertain or insufficient evidence supporting their use should be particularly scrutinized.” He further noted that, “[t]he continued growth in corticotropin [Acthar] use is peculiar given its very high cost, widespread negative media coverage, and notable lack of evidence supporting its use over lower-cost synthetic

corticosteroids. Our experience suggests aggressive marketing of the drug partly accounts for increasing use.”

258. The JAMA study also noted an association between providers who received higher compensation and their writing more Acthar prescriptions—and the Acthar prescriptions written by these frequent prescribers accounted for \$200 million in Medicare spending during the period that the study examined.

259. Indeed, this study also found that from 2011 to 2015, spending on Acthar increased ten-fold, totaling more than \$1.3 billion for just several thousand Medicare patients. Upon information and belief, and given the continued marketing of Acthar by Mallinckrodt pursuant to the marketing scheme alleged by the Qui Tam Relators, those numbers have increased since 2015.

260. The conclusion of the JAMA study was that most nephrologists, neurologists, and rheumatologists who frequently prescribe Acthar received Acthar-related payments from Mallinckrodt, suggesting that financial conflicts of interest may be driving the prescription and use of Acthar. Indeed, as noted by Dr. Hartung, “we observed a positive association between the amount of money paid to these prescribers, their prescribing intensity, and corticotropin [Acthar] expenditures in the Medicare program with a return on investment for Mallinckrodt of about 5:1.”

261. Consistent with the JAMA study’s conclusions, in October of 2014, Mallinckrodt had a briefing with its investors. At that briefing, Dr. Gary Phillips, the Senior Vice President, and President of Mallinckrodt's Autoimmune and Rare Disease Business, pledged, “[t]he one thing that you can be sure of is that the awareness and the evidence of the product will just expand dramatically over the next year.”

262. Dr. Phillips presented PowerPoint slides detailing the company's strategy, including the need to get Acthar to its "underserved patient population" in rheumatology, pulmonology, ophthalmology, dermatology and kidney disease.

263. One graphic showed 9,000 patients were currently being treated with Acthar and that 300,000 people had "addressable but currently untreated" conditions. The slide also noted a total of 4 million Americans suffered from "Acthar indicated conditions."

264. The aggressive marketing push outlined by Mallinckrodt executives in that October 2014 investor meeting appears to have paid off: Medicare spent more than \$600 million on more than 12,000 Acthar claims in 2016 – more than double the numbers from 2013, the year before Mallinckrodt's purchase of Questcor. Many of those prescriptions were made by rheumatologists, nephrologists, and neurologists – the very type of doctors Mallinckrodt executives said they planned to target in October 2014 to capture the "underserved patient population."

265. In 2018, Local 420 began paying for Acthar prescriptions for the wife of one of its members for the treatment of a rheumatic disorder which as identified by Mallinckrodt as an "underserved" area.

266. Few medical providers have come forth to blow the whistle on Mallinckrodt's tactics. One brave doctor, Dr. Megan Clowse of the Duke University School of Medicine, wrote last year that "[w]e also know from personal experience that Acthar's manufacturer is actively looking for clinical researchers open to perform more, small, open-label, nonrandomized trials of their drugs." In other words, even doctors not receptive to Mallinckrodt's marketing scheme are approached. Discovery of Mallinckrodt's records will enable Plaintiff and the Class to ferret out the chaff from the wheat, the ethical doctors from the spokes-doctors.



267. One such spokes-doctor, Dr. William Shaffer, a neurologist in Greeley, Colorado, was the highest prescriber of Acthar in 2012. He wrote only 78 prescriptions for the drug, but the prescribed Acthar cost Medicare \$4,000,000.

268. Dr. Shaffer has been paid handsomely by Mallinckrodt for his loyalty to the company. The very next year, Dr. Shaffer was rewarded by being engaged by Mallinckrodt to speak as a KOL on multiple occasions, in multiple places, as part of all-expense paid trips sponsored by the company. For instance, he was flown to the east coast to conduct four speaking engagements with dozens of the doctors over the course of two days, January 24-25, 2013. He spoke in Reston and Falls Church, Virginia, and then Bethesda, Maryland.

269. But Dr. Shaffer was far from alone. He is just one of dozens of highly-compensated Mallinckrodt spokes-doctors, all important spokes in the wheel of Mallinckrodt's RICO conspiracy, as they are all connected to Mallinckrodt's self-described "HUB" and all profit as integral "spokes" in Mallinckrodt's marketing and sales scheme.

**4. Leading "KOLs" for Mallinckrodt Promote for "New Indications" through a Scheme of "White Coat Marketing".**

270. Mallinckrodt sought help in effectuating their scheme and conspiracy by seeking KOLs in the medical fields where Acthar was not the preferred course of treatment. Indeed, Acthar was not approved by the FDA for the long-term treatment of any disease; instead, Acthar has had a narrow indication since 1952 for the treatment of only acute exacerbations of disease and flare-ups.

271. As Express Scripts' 2018 Prior Authorization Policy acknowledged, "data and guidelines do not suggest that Acthar has a substantial role in therapy" for most of the diseases for which Mallinckrodt promotes and sells Acthar. Instead, Express Scripts found in late 2017,



as the FDA found in 2010, that “[f]urther data are needed before use in other areas [beyond IS and MS] can be recommended.” *Id.* at 4 (brackets added).

272. To overcome this lack of data to support to use of Acthar to treat “new indications”, and to support its off-label marketing effort, Mallinckrodt engaged KOLs strategically situated throughout the country, initially to determine whether there was a viable potential market for Acthar with neurologists, nephrologists and rheumatologists.

273. In order to cultivate KOLs for its white coat marketing scheme, Mallinckrodt directed its sales force call on select neurologists, nephrologists and rheumatologists to discuss the treatment of new indications of disease with leading practitioners in these fields, and to begin developing and sharing the data on treatment with Acthar.

274. Mallinckrodt then began “[w]orking with KOLs who have expressed interest in generating such data” to support the off-label use of Acthar to treat such “new indications”. This became a “major focus” for Mallinckrodt after it acquired Questcor.

275. This new marketing initiative into off-label promotion of Acthar for “new indications” was made possible by the “success of the new Acthar pricing strategy” by which “significant funds [were] now available for the first time to support Acthar-related research” by paying “KOLs to explore areas of mutual research interest.” *Id.* In other words, the profits realized by the implementation of the “new strategy” in 2007 for IS treatments made it possible for Mallinckrodt to pay doctors to serve as KOLs as part of the Mallinckrodt white coat marketing strategy into rheumatology, nephrology and other areas.

276. The practice of “white coat marketing” was identified by the Office of Inspector General (OIG) of the federal government as a potential area of fraud and abuse as early as 1991.

See, e.g., OIG Advisory Opinion No. 11-08, issued June 12, 2011, at 6 (citing 56 Fed. Reg. 35952, 35974 (July 29, 1991)). As described in Advisory Opinion No. 11-08:

The fraud and abuse risks are compounded where, as here, a physician or other health care professional is involved in the marketing activity – a practice sometimes referred to as “white coat” marketing. White coat marketing is closely scrutinized under the anti-kickback statute because physicians and other health care professionals are in an exceptional position of public trust and thus may exert undue influence when recommending health care-related items or services – especially when marketing to their patients. See, e.g., 56 Fed. Reg. 35952, 35974 (July 29, 1991). Given the nature of these relationships, when physicians or other health care professionals market items and services to their patients, patients may have difficulty distinguishing between professional medical advice and a commercial sales pitch.

**5. Mallinckrodt KOLs Working for Mallinckrodt as Spokes-Doctors in Pennsylvania and Throughout the Country.**

277. While it is impossible without the benefit of discovery to identify and describe the full nature and extent of Mallinckrodt’s unlawful white coat marketing scheme for the off-label promotion of Acthar – as only discovery will reveal the facts that lie within Mallinckrodt’s exclusive custody and control – specific examples demonstrate that the scheme was widespread in Pennsylvania and elsewhere.

**a. Dr. David R. Mandel in Chardon, Ohio**

278. Dr. David R. Mandel (“Dr. Mandel”), is a rheumatologist with offices located at 320 Center Street, Chardon, Ohio.

279. Public reports reveal that Dr. Mandel was regarded as a top prescriber of Acthar making up 1% of all prescriptions with 14 patients receiving Acthar.

280. According to the website sponsored by Propublica,<sup>7</sup> Mallinckrodt claims Dr. Mandel was only paid the following disclosed sums for his promotional activity on behalf of Mallinckrodt in selling Acthar to other doctors throughout the country:

Aug. 2013 - Dec. 2013	\$16,653
Jan. 2014 - Dec. 2014	\$3,077
Jan. 2015 – Dec. 2015	\$3,032
Jan. 2016 – Dec. 2016	\$126

281. However, in 2014, Dr. Mandel pled guilty and was sentenced to probation and paid \$650,000 for causing the shipment of “misbranded” drugs.

282. Mallinckrodt has been sued by a former employee, Barry Franks. In Franks’ Complaint, he details the unlawful conduct of Dr. Mandel, along with another Mallinckrodt sales representative, identified as “Smith”. It is believed and therefore averred that “Smith” is actually Christopher Sender, the Mallinckrodt sales manager in charge of the Ohio area where Dr. Mandel practices.

283. As a highly compensated KOL and spokes-doctor for Mallinckrodt, Dr. Mandel actively promoted the sale of Acthar to patients and TPPs for unapproved uses and doses in order to get TPPs, like Plaintiff and the Class, to pay for Acthar at inflated prices. Specifically, Dr. Mandel promoted the sale of Acthar for RA.

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<sup>7</sup> See <https://projects.propublica.org/docdollars/> According to Propublica, “[p]harmaceutical and medical device companies are required by law to release details of their payments to a variety of doctors and U.S. teaching hospitals for promotional talks, research and consulting, among other categories. Use this tool to search for general payments (excluding research and ownership interests) made from August 2013 to December 2016.”

284. In promoting Acthar for unapproved uses and doses in the treatment of RA, Dr. Mandel misrepresented and deceived patients and payors about the Acthar MOA and the limited FDA approval.

285. Dr. Mandel specifically wrote to payors, after his initial prescriptions for Acthar were denied due to the prior authorization TPPs had placed on Acthar to prevent high payments for specialty drugs, especially for off label indications. Working with Mallinckrodt's HUB, UBC, however, Dr. Mandel sent letters appealing the TPP's denial decisions. Such letters were sent to UBC, to be used with TPP's, through use of the mail, including email, and wires. They contained false and misleading statements about the limited FDA approval of Acthar and its purported MOA.

286. Specifically, as to the FDA approval, Dr. Mandel would write to TPPs that Acthar was approved for specific RA indications, when it was not. As for the Acthar MOA, Dr. Mandel would write to TPPs misrepresenting that the Acthar MOs was known, when it was not. Indeed, he would provide lengthy explanations about the Acthar MOA, which explanations were not based upon any FDA approval or any FDA approved clinical studies.

287. The letters sent and other communications had between Dr. Mandel and TPPs in order to appeal the denial of Acthar were vetted by and shared with Mallinckrodt and UBC. Mallinckrodt and UBC were fully aware of Dr. Mandel's misrepresentations, and yet took no steps to stop or correct them, to the detriment of the TPPs who paid for the Acthar based upon such misrepresentations. Instead, Mallinckrodt rewarded Dr. Mandel with increasing KOL speaking engagements, for which he was well compensated.

288. Based upon the JAMA study and other evidence of Mallinckrodt's KOL program for Acthar, including the above-described example of Dr. Mandel for which specific evidence is

available, it is averred that other KOLs conducted themselves in the same manner. That is, Mallinckrodt-paid KOLs misrepresented and deceived TPPs about the MOA for Acthar and the limits of its FDA approval, in order to get TPPs to pay for Acthar for unapproved uses and doses. These false and misleading communications were routed to TPPs through UBC via facsimile.

289. Plaintiff and the Class were harmed by such conduct, either directly through the promotional effort of Mallinckrodt KOLs and MSLs, or indirectly through their intercession in the care of beneficiaries of Plaintiff and the Class through the ASAP program and otherwise.

290. Plaintiff and other clients of the Plaintiff's counsel, along with unnamed members of the Class paid the inflated prices for Acthar for indications in MS, NS, SLE and RA pursuant to the fraudulent pricing, marketing and sales scheme alleged.

**291. MANDEL PROSECUTION FOR MISBRANDING**

**b. Dr. James Tumlin in Chattanooga, Tennessee and Acument's Inflated Payments for Acthar**

292. In a related case filed in Tennessee state court by the same undersigned Plaintiff's counsel, the plaintiff there, Acument Global Technologies, Inc. ("Acument") has specifically pled that Mallinckrodt hired Dr. James A. Tumlin, M.D. ("Dr. Tumlin") as a leading KOL to develop supporting data using his existing patients as test subjects in a non-FDA-approved, open label clinical study.

293. Mallinckrodt also paid Dr. Tumlin to travel the country, instructing other doctors on the unapproved uses of Acthar for nephrology and soliciting such doctors to become KOLs for Mallinckrodt.

294. Mallinckrodt has paid Dr. Tumlin handsomely for such work on behalf of the company. He has been paid hundreds of thousands of dollars.

295. Dr. Tumlin is a physician who specializes in nephrology and is associated with Nephrology Associates of Chattanooga located at 2300 E. 3rd Street, Chattanooga, Tennessee. He is founder and medical director of Southeast Renal Research Institute (SERRI) since 2005. The institute was brought to Chattanooga in 2008 and merged with Nephrology Associates' Research Department.

296. As with its other KOLs, Mallinckrodt contracted with Dr. Tumlin to conduct clinical studies of his patients using Acthar to treat their NS. This engagement was not to conduct any FDA-approved clinical study. Instead, it was intended by Mallinckrodt to pay Dr. Tumlin to conduct clinical studies of his own patients by prescribing Acthar to them for unapproved uses and doses to treat their nephrotic syndrome in order to learn about the effects of Acthar on their disease and assist Mallinckrodt in developing anecdotal clinical data with which to promote Acthar's use to other nephrologists. It is believed that one such patient was a beneficiary of Acument.

297. The 2009 contracted study was titled "A Randomized, Placebo-Controlled, Parallel-Group, Double-Blind Study of H.P. Acthar Gel (Acthar) in Treatment-Resistant Subjects with Persistent Proteinuria and Nephrotic Syndrome Due to Idiopathic Membranous Nephropathy (iMN)" (hereinafter, "Tumlin 2009 Randomized Study"). It is believed and therefore averred that Dr. Tumlin "enrolled" 15 patients for this study. While Acument's beneficiary had iMN, it is unknown whether Acument's beneficiary was included among the 15 patients Dr. Tumlin treated with Acthar as part of this contracted study. Only discovery in these cases will reveal the truth.

298. However, it is known Dr. Tumlin did not charge either the beneficiary or Acument for the Acthar he prescribed in 2011. Instead, it is believed and therefore averred that

Mallinckrodt provided the drug for free in order that Dr. Tumlin could develop data to assist in its marketing and sales of Acthar to other nephrologists.

299. Dr. Tumlin's work on behalf of Mallinckrodt became a centerpiece of its marketing plan for nephrologists, not just in Tennessee, where Dr. Tumlin's practice, Southeast Renal Research Institute, was located in Chattanooga, but throughout the country, including Pennsylvania.

300. As with other KOLs, Dr. Tumlin travelled across the country on all expenses paid trips funded by Mallinckrodt to promote the use of Acthar for NS and other disease states for which there were no clinical studies to support the treatment. Instead, Dr. Tumlin cited to other doctors his own anecdotal experience with his patients, about which he published in two papers, the Tumlin 2001 Study and the Tumlin 2013 Pilot Study.

301. While it is not yet known the total dollars Mallinckrodt paid Dr. Tumlin for these two "studies" which led to published articles, those monies were only part of Dr. Tumlin's compensation for working for Mallinckrodt.

302. For instance, Dr. Tumlin conducted a third study titled "Safety and Efficacy of Acthar Gel on Albuminuria and Urinary Transforming Growth Factor Excretion in Type II Insulin Requiring Diabetics with Nephrotic Range Proteinuria: A Pilot Study". Mallinckrodt paid Dr. Tumlin for that study.

303. In its prior authorization update released in 2018 – 9 years after Mallinckrodt began white coat marketing of Acthar through KOLs like Drs. Mandel and Tumlin– Express Scripts stated that Acthar should not have been "recommended for approval" by any doctor, including Dr. Tumlin, for treatment of iMN in patients.

304. In fact, Express Scripts cited Dr. Tumlin’s 2 published papers sponsored and paid for by Mallinckrodt: the Tumlin 2011 Study and the Tumlin 2013 Pilot Study,<sup>8</sup> in concluding that “very limited data in nephrotic syndrome have studied the use of Acthar, in patients with diagnoses including idiopathic membranous nephropathy (iMN)...”.

305. Mallinckrodt MSLs and sales representatives used Dr. Tumlin’s open label studies to promote the sale of Acthar for off-label uses and doses. Similarly, UBC was trained with Dr. Tumlin’s studies and used them in discussing the use of Acthar for unapproved uses and doses with patients, providers and TPPs.

306. According to the website sponsored by Propublica,<sup>9</sup> Dr. Tumlin was paid by Mallinckrodt at least the following disclosed sums for his promotional activity on behalf of Mallinckrodt in selling Acthar to other doctors throughout the country, apart from the monies he has earned conducting “clinical studies” of his patients:

Aug. 2013 - Dec. 2013	\$15,318
Jan. 2014 - Dec. 2014	\$27,733
Jan. 2015 – Dec. 2015	\$28,839
Jan. 2016 – Dec. 2016	\$50,840

<sup>8</sup> Bomback AS, Tumlin JA, Baranaski J, et al. Treatment of nephrotic syndrome with adrenocorticotrophic hormone (ACTH) gel. *Drug Des Devel Ther.* 2011; 5:147-153 (“Tumlin 2011 Study”).

<sup>9</sup> See <https://projects.propublica.org/docdollars/> According to Propublica, “[p]harmaceutical and medical device companies are required by law to release details of their payments to a variety of doctors and U.S. teaching hospitals for promotional talks, research and consulting, among other categories. Use this tool to search for general payments (excluding research and ownership interests) made from August 2013 to December 2016.”



307. On multiple occasions, Dr. Tumlin was paid twice by Mallinckrodt for the same services and reimbursements, in an obvious effort to overpay Dr. Tumlin for his “consulting” activities.

308. For instance, on May 23, 2016, Propublica reports that Dr. Tumlin received two payments from Mallinckrodt for “promotional speaking” in the amount of \$3,400 each. He also received two equal payments of \$2,050 for “promotional speaking” July 2, 2015.

309. On June 17, 2015, Mallinckrodt paid Dr. Tumlin the following sums for “travel and lodging” for just one day: \$537, \$529, \$393, \$393, \$276, \$87, \$50, \$50, \$30, \$30 and \$22.

310. Based on the Propublica information, it is believed that Dr. Tumlin travelled the country for Mallinckrodt to promote Acthar use in nephrology. Mallinckrodt paid with substantial “honoraria” paid, totaling up to \$5,000 at time, for his time and effort.

311. The specific dates, locations and payments relating to these Dr. Tumlin’s consulting for Mallinckrodt as a leading KOL lies within the exclusive control of Mallinckrodt and Dr. Tumlin, who have a joint interest in concealing the details of their relationship. Only discovery will reveal these details to Plaintiff and the Class.

**c. Dr. Gary Clauser in Allentown, Pennsylvania And IUOE Local 542’s Inflated Payments for Acthar**

312. Gary Clauser, M.D. is a board-certified neurology specialist in the Lehigh Valley Physician Group (LVPG) with offices located at 1250 S. Cedar Crest Boulevard, Suite 405, Allentown, Pennsylvania. LVPG has additional offices located in Bethlehem and Palmer Township, Pennsylvania.

313. In July 2011, Dr. Clauser treated a patient covered by the International Union of Operating Engineers Local 542 (“IUOE Local 542”) located in Fort Washington, Pennsylvania. IUOE Local 542 has sued Mallinckrodt individually in Pennsylvania state court. Earlier this

year, the Court of Common Pleas of Montgomery County denied Mallinckrodt's Preliminary Objections seeking to have the case dismissed. Since that time, the case has been proceeding through discovery.

314. Because of the marketing and sales efforts by Mallinckrodt's sales representatives, including Art Venio, Dr. Clauser utilized the Acthar Start Form with his patients, including the IUOE Local 542 patient treated with Acthar. As a result, UBC coordinated the payment for Acthar by IUOE Local 542 on behalf of Mallinckrodt at the inflated AWP price set by Mallinckrodt. As a result, IUOE Local 542 and its beneficiary were harmed by the scheme and conspiracy of Defendants through their direct participation in the ASAP program.

315. Dr. Clauser has treated multiple patients in Pennsylvania with Acthar. It is believed and therefore averred that such patients and their TPPS were subjected to and harmed by the scheme and conspiracy allege herein by Dr. Clauser's role as a highly paid KOL for Mallinckrodt, and his utilization of Acthar Start Forms with his patients. Dr. Clauser has treated patients with Acthar on at least the following dates for the identified conditions: June 9, 2014 (MS); September 10, 2014 (MS); September 12, 2014 (MS); October 9, 2014 (MS); October 15, 2014 (MS); February 24, 2015 (MS); April 20, 2015 (MS); June 3, 2015 (MS); and June 8, 2015 (MS).

316. Dr. Clauser prescribed Acthar for an IUOE Local 542 beneficiary, and charged the inflated AWP-based price as set by Mallinckrodt by submitting the prescription through IUOE Local 542's PBM, Express Scripts. IUOE Local 542 paid the AWP-based price charged.

317. Specifically, Dr. Clauser prescribed an unapproved 5-day dose of Acthar to treat a patient with MS, who was also a beneficiary of IUOE Local 542. Dr. Clauser filled out an

Acthar Start Form on June 29, 2011, listing “80 units/day x 5 days” for MS, and faxed the form to UBC to obtain coverage and payment from IUOE Local 542, which it did.

318. Dr. Clauser held a meeting with Mallinckrodt in his office in Allentown on Tuesday, January 8, 2013. Also in attendance were his employees, nurse practitioner Jean Bakke-Cain and registered nurse Grace Connelly.

319. The meeting was arranged by Mallinckrodt’s sales representative for the Lehigh Valley, Art Venio. Also invited to attend was one of Mallinckrodt’s top 10 KOLs in the country, Dr. Ruwani Gunawardane, a neurologist from Fulton, Maryland. While it is unknown what was said at the meeting, based on the express goals of the KOL program, it is likely that Dr. Gunawardane was brought from Maryland to Allentown to further train Dr. Clauser in the “art” of being a top Mallinckrodt KOL and spokes-doctor. It is believed and therefore averred Dr. Gunawardane also taught Dr. Clauser about the off-label uses and doses of Acthar for the treatment of his patients, including for the treatment of MS. Dr. Gunawardane specifically thanked Dr. Clauser and his staff at Lehigh Neurology about “perspectives on MS relapses and Acthar.”

320. Only discovery will reveal if Dr. Gunawardane has been paid more than a consulting fee, honoraria and travel expenses, such as whether she has been paid additional monies based on the Acthar sales generated by Dr. Clauser in the wake of her visit to him. Such a “pyramid scheme” would perhaps explain how Dr. Gunawardane has been able to generate more than \$100,000 a year working for Mallinckrodt as a KOL, in addition to maintaining a healthcare practice in Maryland.

321. According to ProPublica, Dr. Gunawardane has been paid a staggering \$1,111,326 as a paid consultant to drug companies, \$332,000 of which was paid by

**Mallinckrodt.** She is among the top eight largest prescribers of Acthar in the country, and is among the highest paid of Mallinckrodt's KOLs.

322. Specifically, according to CNN, Dr. Gunawardane "received 502 payments worth \$332,393.36 -- nearly half was compensation for services, about a third was honoraria, about a sixth was for travel and lodging, and the rest was for consulting, education and food and beverage. Gunawardane filed 38 claims resulting in \$1,329,002.84 in Medicare coverage."<sup>10</sup> Dr. Gunawardane declined to comment when confronted by CNN. *Id.*

323. Dr. Clauser became a Mallinckrodt "spokes-doctor" and KOL after the January 8, 2013 meeting with Mallinckrodt and Dr. Gunawardane. Dr. Clauser has been a highly KOL for Mallinckrodt for years.

324. According to Propublica, which has only published data since the second half of 2013, Dr. Clauser was paid by Mallinckrodt at least the following disclosed sums for his promotional activity on behalf of Mallinckrodt in promoting the sale of Acthar to other doctors throughout Pennsylvania and New Jersey:

Aug. 2013 - Dec. 2013	\$9,124
Jan. 2014 - Dec. 2014	\$26,959
Jan. 2015 – Dec. 2015	\$8,727
Jan. 2016 – Nov. 2016	\$18,286

<sup>10</sup> <https://www.cnn.com/2018/06/29/health/acthar-mallinckrodt-medicare-claims-doctor-payments/index.html>

325. In the first half of 2013 alone, since the meeting with Dr. Gunawardane, Dr. Clauser served as a Mallinckrodt KOL on at least the following occasions in the following places:

January 18, 2013	Wilkes Barre, PA
March 22, 2013	East Norriton, PA
April 16, 2013	Bridgewater, NJ
April 18, 2013	Sellersville, PA
April 29, 2013	Manhattan, NY
May 14, 2013	Brooklyn, NY
May 21, 2013	King of Prussia, PA
June 26, 2013	Brooklyn, NY
August 1, 2013	Center Valley, PA

326. On multiple occasions, Dr. Clauser was paid twice by Mallinckrodt for the same services and reimbursements, in an obvious kickback to the doctor.

327. Based on the Propublica information, Mallinckrodt paid Dr. Clauser substantial “honoraria” and “consulting” fees, totaling up to at least \$59,423, for his time and effort.

328. The specific dates, locations and payments relating to Dr. Clauser’s consulting for Mallinckrodt as a KOL lies within the exclusive control of Mallinckrodt and Dr. Clauser, who have a joint interest in concealing the details of their relationship. Only discovery will reveal these details to Plaintiff and the Class.

**d. Dr. Steven Urbaniak in Langhorne, Pennsylvania And IUOE Local 542’s Inflated Payments for Acthar**

329. Steven Urbaniak, DO. is a board-certified neurologist with Oxford Neurology, LLC located at 940 Town Center Drive, Suite F50, Langhorne, Pennsylvania. Dr. Urbaniak is also on staff at St. Mary Medical Center in Pennsylvania.

330. Beginning in March 2013, Dr. Urbaniak treated a patient covered by IUOE Local 542. Dr. Urbaniak prescribed Acthar for the patient, and charged the inflated AWP-based price

as set by Mallinckrodt by submitting the prescription through IUOE's PBM, Express Scripts. IUOE Local 542 paid the AWP-based price charged.

331. Because of the marketing and sales efforts by Mallinckrodt's sales representatives, including Stacyann Clancy, Dr. Urbaniak utilized the Acthar Start Form with his patients, including the IUOE Local 542 patient treated with Acthar. As a result, UBC coordinated the payment for Acthar by IUOE Local 542 at the inflated AWP prices set by Mallinckrodt. As a result, IUOE Local 542 and its beneficiaries were harmed by the scheme and conspiracy of Defendants through their direct participation in the ASAP Program.

332. Specifically, it is believed and therefore averred that Dr. Urbaniak prescribed an unapproved 5-day dose of Acthar to treat MS in a beneficiary of IUOE Local 542, with the direct involvement and assistance of Mallinckrodt and UBC in securing payment at the inflated AWP for Acthar and IUOE Local 542.

333. Dr. Urbaniak has treated multiple patients in Pennsylvania with Acthar. It is believed and therefore averred that such patients and their TPPS were subjected to and harmed by the scheme and conspiracy alleged here in by Dr. Urbaniak's role as a highly-paid KOL for Mallinckrodt, and his utilization of Acthar Start Forms with his patients. Dr. Urbaniak has treated patients with Acthar for the treatment of MS and MS relapses on at least the following occasions: July 22, 2014; October 6, 2014; October 28, 2014 and December 19, 2014.

334. Stacyann Clancy is specifically identified by Relator Strunck and Pratta as having engaged in the unlawful conduct alleged in this case. *See* Struck and Pratt Cmplt, at ¶¶ 133-134.

335. Dr. Urbaniak held a meeting in his office in Langhorne on Tuesday, January 8, 2013. Also, in attendance was another doctor by the same last name, Kathy Urbaniak, M.D. At least 8 other people from Oxford Neurology also attended.

336. The meeting was arranged by Questcor's sales representative, Stacyann Clancy, for a discussion with Mallinckrodt leading KOL, Dr. Ruwani Gunawardane.

337. While it is unknown what was specifically discussed at the 2013 meeting, it is known that Dr. Gunawardane presented on the topic of "MS Relapses and the MCR System." Dr. Urbaniak has been a KOL for Mallinckrodt for years.

338. According to Propublica, Dr. Urbaniak was paid by Mallinckrodt at least the following disclosed sums for his promotional activity on behalf of Mallinckrodt in selling Acthar to other doctors throughout Pennsylvania:

Aug. 2013 - Dec. 2013	\$10,241
Jan. 2014 - Dec. 2014	\$3,815
Jan. 2015 – Dec. 2015	\$2,010
Jan. 2016 – Nov. 2016	\$107

339. Since the meeting with Dr. Gunawardane, Dr. Urbaniak served as a Mallinckrodt KOL on the following occasions in the following places:

March 13, 2013	New Hope, PA
May 30, 2013	Warrington, PA
July 11, 2013	Philadelphia, PA

340. Based on the Propublica information, Mallinckrodt paid with substantial "honoraria" and "consulting" fees, totaling up to \$59,423, for his time and effort.

341. The specific dates, locations and payments relating to these Dr. Urbaniak's consulting for Mallinckrodt as a KOL lies within the exclusive control of Mallinckrodt and Dr.

Urbaniak, who have a joint interest in concealing the details of their relationship. Only discovery will reveal these details to Plaintiff and the Class.

**e. Dr. Irene Greenhouse Jamison, Pennsylvania And IUOE Local 542's Inflated Payments for Acthar**

342. Irene Greenhouse, M.D. is a board-certified neurology specialist with offices located at 2370 York Road, Jamison, Pennsylvania.

343. In July 2014, July 2015 and throughout 2017, Dr. Greenhouse treated a patient covered by IUOE Local 542.

344. Dr. Greenhouse prescribed Acthar for an IUOE Local 542 beneficiary, and charged the inflated AWP-based price as set by Mallinckrodt and as charged by UBC by filling out multiple Acthar Start Forms and submitting them to UBC via facsimile in order to engaged the ASAP program established by Defendants as part of their scheme to defraud TPPs. On the forms, Dr. Greenhouse listed the disease state as "multiple sclerosis", but claimed each time that the Acthar treatment was allegedly for an MS exacerbation, in order to try to bring the prescription within the Acthar approved label. However, as set forth below, there was insufficient evidence presented by Dr. Greenhouse to support her claim of an MS exacerbation.

345. Further, each time, Dr. Greenhouse prescribed an unapproved 5-day dose of Acthar to treat the MS. As described above by Relators Strunck and Pratta, this put the patient at unnecessary risk, in view of other available, safe and effective, and even cheaper medicines. Specifically, this particular patient was trying to become pregnant. Acthar's label specifically warns that "H.P. Acthar has been shown to have an embryocidal effect. There are no adequate and well-controlled studies in pregnant women. H.P. Acthar should be use during pregnancy only if the potential benefit justifies the potential risk to the fetus."



346. It is believed that Dr. Greenhouse never stated to UBC, or IUOE Local 542, in her submissions through the ASAP that she had made any determination that “the potential benefit justifies the potential risk to the fetus.”

347. It is believed and therefore averred that at some point prior to 2013, Dr. Greenhouse was trained in the “art” of being a top Mallinckrodt KOL and spokes-doctor by someone at Mallinckrodt, and likely another as-yet-unknown KOL.

348. Only discovery will reveal if Dr. Gunawardane was that KOL, as she has trained two other area Pennsylvania neurologists, Dr. Clauser and Dr. Urbaniak, both of whom treated IUOE beneficiaries suffering from MS with Acthar.

349. It is known that Dr. Greenhouse has been paid thousands of dollars acting as a Mallinckrodt KOL.

350. According to Propublica, which has only published data since the second half of 2013, Dr. Greenhouse was paid by Mallinckrodt at least the following disclosed sums for her promotional activity on behalf of Mallinckrodt in promoting the sale of Acthar to other doctors:

Aug. 2013 - Dec. 2013	\$35,705
Jan. 2014 - Dec. 2014	\$48,878
Jan. 2015 – Dec. 2015	\$50,278
Jan. 2016 – Nov. 2016	\$37,250

351. The specific dates, locations and payments relating to these Dr. Greenhouse’s consulting for Mallinckrodt as a KOL lies within the exclusive control of Mallinckrodt and Dr. Greenhouse, who have a joint interest in concealing the details of their relationship. Only discovery will reveal these details to Plaintiff and the Class.

352. It is known that Dr. Greenhouse has been prescribing Acthar since at least 2012, when Mallinckrodt and UBC were rolling out their schemes to promote Acthar for unapproved uses and doses in the treatment of lupus. For instance, on October 3, 2012, while Dr. Greenhouse was working for Meadowbrook Neurology on Huntingdon Pike in Huntingdon Valley, Pennsylvania she prescribed Acthar for the treatment of lupus in a patient.

353. Critically, Dr. Greenhouse asked UBC to have Mallinckrodt send her an MSL. UBC's note states "Please have a Rheum msl follow up." In other words, Defendants utilized Mallinckrodt's MSLs in their dealings with Dr. Greenhouse.

**i. The case of "Patient A"**

354. In this case, there is at least one example of a patient's safety being potentially put at risk, contrary to the approved Acthar label, as a direct and proximate result of the Defendants' unlawful conduct alleged herein.

355. A beneficiary of IUOE Local 542, known as "Patient A" to protect the patient's identity and HIPAA rights,<sup>11</sup> has been treated by Dr. Irene Greenhouse of Jamison, Pennsylvania for MS. As explained below, Dr. Greenhouse is a Mallinckrodt KOL. Dr. Greenhouse has been paid tens of thousands of dollars by Mallinckrodt to act as a "spokes-doctor" for the company for years. Specifically, on information and belief, Dr. Greenhouse has been paid by Mallinckrodt to speak to other doctors about her experience in prescribing Acthar for the treatment of MS exacerbations, including treatment with an unapproved, 5-day dosing regimen, like she has prescribed for her MS patients for years.

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<sup>11</sup> Defendants are fully aware of the identity of Patient A, as they alone possess and control the documents from which the above facts were gleaned. They only way Plaintiff and its counsel will be able to glean such facts about Local 420's own patient, and the patients of other TPPs in the Class, will be through discovery in this case.

356. In 2017, Dr. Greenhouse prescribed an unapproved, 5-day dosing regimen of Acthar for the treatment of a supposed MS exacerbation in Patient A. She did this on multiple occasions in 2017. Dr. Greenhouse had previously prescribed the same unapproved, 5-day dosing regimen for Acthar to Patient A for a supposed MS exacerbation in the years 2014 and 2015, while Mallinckrodt and UBC were actively promoting Acthar for such unapproved dose. Specifically, she prescribed Acthar to Patient A for a 5-day dose in July of 2014 and July of 2015.

357. Both times, IUOE Local 542 was charged the inflated, AWP-based price for Acthar by UBC and Mallinckrodt, despite the fact the Acthar was not approved for such a treatment.

358. Both times, IUOE Local 542 paid a discounted price off the AWP, pursuant to its plan with Express Scripts. These amounts were \$32,180.68 for the July 2014 prescription, and \$34,653.95 for the July 2015 prescription, respectively.

359. The inflated AWPs at the time for Acthar were \$37,951.20 and \$40,840.80, respectively.

360. Patient A paid co-pays of \$40.00 and \$20.00 for these administrations, respectively. However, Patient A was not charged a co-pay for the 2017 prescriptions. Instead, Patient A was transferred to Mallinckrodt's Patient Assistance Program ("PAP"), which PAP was run by UBC. Patient A was approved by UBC and Mallinckrodt for long-term PAP, meaning Patient A was not required to pay any co-pay for any present or future Acthar prescriptions. Thus, IUOE Local 542 was directly and proximately harmed by the Defendants' conduct in running the PAP as described below, as part of the overall Marketing Enterprise.

361. The FDA-approved label for Acthar states that Acthar may be prescribed for an MS exacerbation. It is unclear that Patient A ever suffered from an MS exacerbation. Such conclusion was questioned by the medical professionals who reviewed Dr. Greenhouse's prescription, and denied such claim.

362. As set forth above, Acthar is only approved to treat MS exacerbations.

363. It is also unclear whether Patient A was treated with approved generic methylprednisolone, or other approved treatments, prior to being prescribed Acthar, as required.

364. In the 2015 prescription, Dr. Greenhouse wrote on the Acthar Start Form that Patient A was given Solu-Medrol IV "2 yrs ago" and that it "failed" then. In other words, in 2013, Patient A was apparently prescribed Solu-Medrol IV. However, she was prescribed Acthar in both 2014 and 2015 without having been prescribed Solu-Medrol or any other approved treatment for MS. Since Acthar is not a "first-line" treatment for MS, a failure of other approved medications is required. But, that was not done by Dr. Greenhouse. Instead, she referenced only an apparent 2013 prior treatment with methylprednisolone as the basis for claiming that Acthar was indicated in later years, to wit, 2014 and 2015. No FDA-approved clinical studies have been done to support such a conclusion.

365. In view of the foregoing, the 2014 and 2015 prescriptions for Acthar were off label in several respects: (1) there was no clear evidence of an MS exacerbation, as required; (2) there was no first-line treatment with an approved medication, and a failure of the same, prior to the Acthar administration, as required; (3) the dose of Acthar prescribed was for an approved, 5-day course of therapy.

366. Beyond the fact that the Acthar prescribed to Patient A in 2014 and 2015 was unapproved, IUOE Local 542 was overcharged for such prescriptions by paying an AWP-based price, as set and charged by Defendants.

367. In 2017, Patient A was prescribed Acthar for an unapproved use and dose a third time.

368. However, this time, IUOE Local 542 had put in place an independent, second level review as part of its mandatory PA. MCMC, LLC of Quincy Massachusetts independently reviews drug claim decisions made by Express Script when challenged on appeal. This was important because, after Dr. Greenhouse prescribed the Acthar to Patient A in March 2017, it was denied.

369. Dr. Greenhouse and UBC then appealed the decision. It was denied a second time.

370. When the claim was first presented in March 2017, IUOE Local 542's PBM denied the claim for the following reasons:

Coverage is provided in situations where that the patient is unable to use high-dose intravenous (IV) corticosteroids; OR, the patient has tried high-dose corticosteroids administered IV (methylprednisolone 500 to 1,000 mg IV daily for 3 to 5 days) and experienced a severe or limiting adverse effect. Coverage cannot be authorized at this time.

371. In other words, IUOE's PBM was not presented with sufficient evidence that Patient A had been given high-dose corticosteroids, like Solu-Medrol IV, in 2017, and that such treatment failed. As a result, IUOE Local 542 coverage was denied.

372. On the second appeal, Dr. Greenhouse's Acthar prescription was denied again on April 15, 2017 by MCMC for the below stated reasons:

Acthar is approved for treating MS relapses in patients who are unable to tolerate or have an adverse reaction to steroids. In Patient A, there is no objective

evidence of a relapse as MRI's were reported [by Dr. Greenhouse] as "There were no lesions per my review". Objective evidence of MS relapse would be contrast enhancing lesions. [Patient A was] also not on any disease modifying therapy, and the symptoms could represent baseline untreated MS and not an exacerbation. The failure of prior steroids was also not clear, and the conversation with the provider [Dr. Greenhouse] was unable to clarify this. Therefore, the requested H.P. Acthar Unit/ML Vile does not meet Prior Authorization (PA) criteria.

Furthermore, the clinical literature also does not support the use as there is no clear MS exacerbation, nor is there a clear failure or adverse reaction to steroids documented. Therefore, the requested H.P. Acthar Unit/ML Vial is not medically necessary outside of PA criteria.

This determination by MCMC constitutes the final review of the services under the terms of The Plan.

373. Dr. Greenhouse prescribed the 5-day dose of Acthar to Patient A despite the fact that Patient A reported "she is trying to get pregnant". In fact, Patient A had suspended her treatment with copaxone to treat her MS because she was trying to become pregnant. The Acthar label specifically warns of potential fetal harm in patients who are pregnant.

374. The label further warns of use of Acthar in "Specific Populations" as a follows:

#### **8.1 Pregnancy**

Pregnancy Class C: H.P. Acthar has been shown to have an embryocidal effect. There are no adequate and well-controlled studies in pregnant women. H.P. Acthar should be use during pregnancy only if the potential benefit justifies the potential risk to the fetus.

375. Despite such clear warning in the Acthar label, Dr. Greenhouse prescribed an expensive, 5-day dose of Acthar for her "likely MS exacerbation and because she failed steroids in the past."

376. In fact, Patient A had only been prescribed steroids 4 years before the 2017 prescription, and there was no clear diagnosis of an MS exacerbation. This was expressly found by MCMC.

377. Yet, in arguing for coverage and payment by IUOE Local 542, on March 27, 2017, Dr. Greenhouse wrote a letter “to whom it may concern” in an effort to get IUOE Local 542 to reverse the PA denial. Dr. Greenhouse faxed the letter to UBC, which in turn forwarded it by use of the wires to as-yet-unknown other persons in an effort to get IUOE Local 542 to reverse its denial of coverage.

378. The letter states, in pertinent part, as follows:

Patient A “is experiencing severe MS exacerbation and has tried and failed IV steroids. Please approve [the] Acthar Gel which is the FDA approved medication for Multiple Sclerosis Exacerbations. ... Please help [Patient A] to get better by allowing [Patient A] to have the medication that is FDA approved.”

379. These statements were false, misleading and deceptive statements in several respects.

380. First, as MCMC found, “there is no objective evidence of a relapse”. Dr. Greenhouse’s statement that Patient A “is experiencing severe MS exacerbation” was unsupported, and “the symptoms could represent baseline untreated MS and not an exacerbation”, as MCMC also found.

381. Second, “the failure of prior steroids was also not clear, and the conversation with the provider [Dr. Greenhouse] was unable to clarify this.” Because “[Patient A was] also not on any disease modifying therapy,” as required, Dr. Greenhouse’s statement that she “has tried and failed IV steroids” was at least deceptive, if not misleading, insofar as it purported to indicate that Patient A recently tried steroids in relation to the claimed 2017 MS exacerbation.

382. Finally, the FDA has not “approved” Acthar for Patient A’s condition, as urged by Dr. Greenhouse.

383. The fact that Defendants coordinated the drafting and sending of a misleading and deceptive letter, by use of the mail and wires, in an effort to bypass IUOE Local 542’s PA in

order to get the TPP to pay for the high-priced Acthar for an unapproved use and dose is direct evidence of their scheme and conspiracy alleged in this case.

384. On May 24, 2017, Dr. Greenhouse filled out a “Prior Authorization Form” provided by Independence Blue Cross (“IBC”), the major medical healthcare provider of Patient A. By the form, Dr. Greenhouse requested coverage for the unapproved, 5-day dose of Acthar for a supposed MS exacerbation. In response to a request for “any member information that may be useful in the decision-making process, Dr. Greenhouse misleadingly reported “my pt [patient] *has tried* and [sic] IV steroids with no relief.” Emphasis added. The statement was misleading because, in plain English, “has” is the third person singular of the present tense of “have”, denoting a present use of IV steroids, not the prior use 4 years ago. As before, Dr. Greenhouse was deliberately trying to convince IBC that Patient A has failed IV steroids in 2017 in order to garner approval of the off-label prescription of Acthar.

385. The blank form was faxed to Dr. Greenhouse on May 24, 2017 at 2:41p.m. Dr. Greenhouse filled out the form and then faxed it to UBC at 3:38p.m. UBC then interceded with IBC to get it to cover the Acthar based on the misleading information provided by Dr. Greenhouse.

**4. Mallinckrodt’s and UBC’s False and Misleading Marketing About the “Mechanisms of Action” for Acthar, in Promoting the Drug for a Wide Range of Unapproved Uses and Doses, Putting Patients at Substantial Risk.**

386. In addition to the lack of proven safety or efficacy for the host of uses and doses that Mallinckrodt and UBC promote Acthar in neurology, nephrology and rheumatology, and the dangerousness of Acthar for such unapproved uses and doses, Mallinckrodt and UBC do not know, and have not known since it acquired the product was acquired by Mallinckrodt in 2001,



the exact “mechanism of action” (“MOA”) for Acthar. In other words, neither Mallinckrodt nor UBC know how Acthar works, even to treat the disease states for which it has been approved.

387. In view of this lack of understanding of the MOA for Acthar, the FDA has mandated the following lines be included on the Acthar label:

## **12 CLINICAL PHARMACOLOGY**

### **12.1 Mechanism of Action**

**The mechanism of action of H.P. Acthar Gel in the treatment of infantile spasms is unknown.**

388. In 2010, in response to Mallinckrodt’s request for approval of the IS indication for Acthar, the FDA expressly found that “the exact mechanism of action for specific indications, such as the treatment of infantile spasms, is not known.” DDMAC Memo at 1 (emphasis added). The FDA made such finding in part due to the fact that the original FDA approval in 1952 was based upon limited clinical evaluation of patients, not any current FDA-approved clinical study standards.

389. Despite these unambiguous findings by the FDA, both Mallinckrodt and UBC misrepresent and deceive providers, patients and TPPs into prescribing, taking and paying for Acthar, respectively, for unapproved uses and doses. Mallinckrodt has repeatedly and consistently misrepresented to the public the “value” of Acthar for specific indications, including the rheumatoid disorder for which the Local 420 beneficiary was prescribed Acthar. UBC coordinates the Acthar prescription from inception to payment, answering all questions posed by providers, patients and TPPs, including questions about the MOA for Acthar and whether it works for the prescribed indication.

390. Internally, Mallinckrodt concedes that, even for IS, the “[e]xact mechanisms of action of ACTH in the treatment of infantile spasms are not fully understood.”

391. Publically, however, Mallinckrodt has falsely and misleadingly promoted the sale of Acthar for the long-term treatment of MS, NS, SLE and RA, despite its limited approval for only acute exacerbations of disease.

392. Indeed, it has been part of Mallinckrodt's long-term business strategy since 2007 to promote the administration of Acthar as a maintenance medication for all indications where it is approved only for the treatment of acute episodes or exacerbations of disease.

393. Prior to the launch of the new strategy in 2007, Mallinckrodt's top executives, at best, had a "rudimentary understanding" of the Acthar MOA. Nevertheless, Mallinckrodt's top executives have routinely misrepresented the value of Acthar for the treatment of specific unapproved indications, despite the FDA's express finding that the MOA is not known.

394. For instance, Mallinckrodt's former COO Steve Carrt has admitted under oath before the FTC that "in 2006, we had only a very rudimentary understanding of either Acthar or synthetic ACTH, understanding both products evolved considerably between 2006 and the present time."

395. Since that time, Mallinckrodt's knowledge of the MOA for Acthar has remained "rudimentary" as to all the disease states for which Mallinckrodt markets and sells Acthar, including and especially those for which there has been no FDA approval.

396. This lack of understanding has not impacted Mallinckrodt's training of UBC's RS's who alone interface with the providers, patients and payors, passing on Mallinckrodt's misleading and deceptive messages about Acthar's purported uses and benefits.

397. In August 2011, when asked directly by investors about the Acthar MOA, Questcor CEO Don Bailey claimed publicly that while "Acthar is an extraction of porcine pituitaries", "it's an undisclosed composition, so that's a trade secret." In other words, he misled

the public that the company would not disclose the “undisclosed composition” of Acthar, when in actuality it was unknown. Bailey further claimed falsely that it is a barrier to entry for competitors to enter the market for ACTH drugs because “there are probably multiple active ingredients” in Acthar, and “there are multiple peptides within Acthar, and they’re undisclosed.” (emphasis supplied).

398. Claiming that the MOA for Acthar is “undisclosed” blatantly misrepresents that it is somehow known by Mallinckrodt, but is not being disclosed by the company because it is supposedly a “trade secret”. It can only be a trade secret if it is known.

399. During that same investor conference call, CEO Bailey was questioned about the MOA for Acthar, and stated “there is actually a fair amount of confusion about the mechanism of action here.” He then passed the question to Christine Clemson, Mallinckrodt MSL. Clemson falsely claimed, “[w]e now know [about Acthar’s] effects in, say, MS are really relevant to its direct effect on the immune system. ...So that’s really the primary, direct effect of Acthar that I discuss in an MS’s office. This is new information....” *Id.* (emphasis supplied).

400. As discussed below, in the case of the beneficiaries of IUOE Local 542, Mallinckrodt’s and UBC’s direct misrepresentations about the purported MOA of Acthar in the treatment of MS exacerbations, through their MSLs/sales representatives and RSs, respectively, led to those beneficiaries receiving unapproved, off label, 5-day dosing of Acthar, for which IUOE Local 542 was forced to pay inflated Acthar prices.

401. Both Mallinckrodt and UBC have encouraged KOLs to speak to patients and TPPs about the MOA of Acthar in order to get them to agree to prescriptions of Acthar for unapproved uses and doses.

402. For instance, in the case of Dr. Mandel, when one of his patients was denied coverage for Acthar on February 27, 2014, he faxed UBC a letter to be sued with the “Clinical Appeals Department” of Express Scripts. In the letter, Dr. Mandel falsely and misleadingly requested coverage for RA – not an RA exacerbation. He claimed “medical necessity” and stated “H.P. Acthar Gel is FDA approved therapy for Rheumatoid Arthritis”. He then stated “Acthar has a very unique mechanism of action”, and proceeded to try to explain what the FDA has mandated on the Acthar label is “unknown.” This letter was used by UBC and Mallinckrodt to get coverage for the patient for RA, an unapproved use.

403. Since the time of the adoption of the new strategy in 2007, Mallinckrodt has been spending money in research to try to discover and understand the MOA of Acthar, all the while promoting the drug as safe and effective for the treatment of diseases for which it has not been approved and for which its efficacy remains unknown, especially at the doses Defendants promote.

404. Despite its longstanding “rudimentary understanding” of the Acthar MOA, Mallinckrodt and UBC have continued to aggressively promote Acthar as both safe and effective, and valuable, for the treatment of a host of diseases, including as long-term, maintenance medication for MS, NS, SLE and RA.

405. Due to their aggressive marketing, Mallinckrodt sales representatives and MSLs, and UBC “Reimbursement Specialists” or “RSs”, are questioned most often by doctors about the efficacy of Acthar and its MOA. Mallinckrodt sales representatives and MSLs, and UBC’s RSs, are trained to misrepresent the truth about Acthar’s MOA and its limited efficacy, and to deceive providers, patients and TPPs about the limited benefits of Acthar.

406. Because it operates Mallinckrodt's HUB for the ASAP program, these same questions are most often posed to UBC. These people are known as "Reimbursement Specialists" or "RSs", and they are assigned to each patient at the time of the Acthar Start Form submission or initial call to UBC. The RS then follows the patient's case until delivery of Acthar and payment by the TPP.

407. The UBC RS directly communicates the false and misleading messages of Mallinckrodt about Acthar, its uses and doses, including off label uses and doses, its supposed benefits in relation to other treatments, and its price and value for the price charged. They do this because they are directly trained by Mallinckrodt MSLs and other employees sent by Mallinckrodt to train all new RSs, and to update the training of existing RSs. UBC RSs are not clinical pharmacists; they have no medical degrees. They are specialists in prescription drug reimbursement. In other words, they specialize in finding ways to get high priced drugs like Acthar paid for by TPPs like Local 420.

408. Neither Mallinckrodt's nor UBC's marketing and promotion of Acthar described in this Complaint has been submitted to, reviewed by, or approved by the FDA, as required.

409. In light of that, as discussed below, the DOJ has chosen to intervene in the lawsuit brought by Qui Tam Relators Strunck, Pratta and Clark to advance the claims of these former Mallinckrodt employees challenging such marketing and sales scheme. See generally, Strunck & Pratta Complaint and U.S. Complaint filed in this Court.

**5. Mallinckrodt Funds "Patient Assistance Programs" Run by UBC to Fund Patients Copays to Circumvent Patient Complaints and TPP Advance Awareness about Acthar's High Prices.**

410. In the U.S. Complaint in Intervention, the government includes detailed allegations about Mallinckrodt's use and employment of free Acthar and copay assistance

through a “scheme [that] allowed the Company to continually raise Acthar’s price yet market it as ‘free’ to patients and doctors, shifting the drug’s ever-increasing cost to Medicare.” Id. at ¶ 2.

411. So too, such Marketing Scheme allowed Mallinckrodt, with UBC’s direct assistance and intervention in running the Mallinckrodt “Patient Assistance Program” or “PAP”, to shift the high costs of Acthar to private payors, like Local 420, IUOE Local 542 and the Class of TPPs and their beneficiaries.

412. As the government alleges, “Mallinckrodt [and UBC] knew that the cost of Acthar would make it difficult to sell because there were cheaper, effective competitor drugs available to treat certain of its approved uses, namely acute exacerbations of multiple sclerosis, lupus and rheumatoid arthritis. Mallinckrodt [and UBC] intended to overcome this difficulty and did so by making the drug ‘free’ to patients by subsidizing their Medicare copayments. By doing so, Mallinckrodt [and UBC] could maintain the high price of Acthar to maximize [their] own sales revenues, but minimize the risk that the drug’s high price would impede doctors and patients from using it.” Id. at ¶ 4 (brackets added).

413. “Mallinckrodt knew that paying copay subsidies to Medicare [and private] patients was illegal. To achieve the same end indirectly, Mallinckrodt paid copay subsidies through a foundation that Mallinckrodt used as a conduit to do so. At the foundation, call the Chronic Disease Fund (now d/b/a Good Days)(collectively “CDF”), Mallinckrodt designed the supposed ‘patient assistance’ funds that paid copays for Acthar only and then funded them through ‘donations’ knowing that its money would be used on Acthar copays to the exclusion of other drugs. Mallinckrodt then sent Medicare [and private payor] patients to CDF in order to receive virtually guaranteed, Mallinckrodt-funded subsidies. The Company also obtained and used data about the number of patients at CDF, the subsidies paid to them, and the amount of

money Mallinckrodt needed to pay to keep covering Acthar copays. Mallinckrodt financed the funds accordingly.” *Id.* at ¶ 5 (brackets added).

414. “Mallinckrodt sent patients to CDF via the Company’s ‘reimbursement hub’ [UBC] for Acthar, called the Acthar Support and Access Program (“ASAP”). Mallinckrodt controlled ASAP, which included a call-center that received referrals for Acthar from physician offices and patients. Mallinckrodt’s sales force took steps to ensure that any Acthar prescriptions were routed through ASAP so the Company could track them. After a referral came in to ASAP, as discussed in more detail [herein], ASAP [via UBC] provided patients with an ‘automatic offering’ of copay assistance via CDF.” *Id.* at ¶ 100 (brackets added).

415. Mallinckrodt set up a specific fund with CDF titled the “MS Acute Exacerbation Fund” for which Acthar was the only listed treatment, in order to ensure that all monies “donated” by Mallinckrodt were earmarked exclusively for patients receiving Acthar. Then, all the provider, working with UBC, need to do was to list the patient’s indication as an “MS Exacerbation” in order to send the patient to CDF for copay assistance with their Acthar copay. The MS Acute Exacerbation Fund had at least twice the available benefit per patient than any other program offered by CDF – at least \$8,000. That was likely to ensure that any copay up to 20% would be covered.

416. As the government alleges, “Mallinckrodt, via ASAP [and the UBC HUB], referred Acthar patients to the fund regardless of whether they were using the drug for an acute exacerbation or on a long-term basis. Internally, Mallinckrodt referred to this longer-term use of Acthar in MS patients as ‘pulse maintenance’ or ‘pulse’ therapy.” *Id.* at ¶102 (brackets added).

417. In this case, Local 420 paid the high cost of Acthar for a beneficiary with RA, while IUOE Local 542 paid the high cost of Acthar for several beneficiaries with MS. With



respect to the alleged PAP conduct, Patient A was provided long term PAP assistance for a supposed MS exacerbation, through a program run by the Chronic Disease Fund (“CDF”) and funded exclusively by money provided by Mallinckrodt. UBC directed Patient A to the CDF for such PAP.

418. Plaintiff alleges that Mallinckrodt employed UBC, the HUB, to coordinate sending the patients to CDF, like Patient A. As described above, once IOUE Local 542’s PA successfully denied the appeal of the coverage decision for a supposed MS exacerbation, Dr. Greenhouse, UBC and Mallinckrodt sought to circumvent that PA by referring Patient A to “Long Term PAP”, as opposed to “Short Term PAP”.

419. Long Term PAP is defined as “PAP support for prequalified patients that are either uninsured” – not Patient A – “or rendered underinsured such that coverage is otherwise unattainable” – not Patient A. In contrast, Short Term PAP is defined as “PAP support for Patients experiencing ... Multiple Sclerosis Acute Exacerbation”, supposedly Patient A according to the diagnosis of Dr. Greenhouse in 2014, 2015 and 2017.

420. If Patient A suffered from MS exacerbation, she could not have been eligible for Long Term PAP. Nevertheless, in accordance with the object of the Marketing and Pricing Schemes alleged, Patient A was referred by Defendants and Dr. Greenhouse to Long Term PAP.

421. Similar to the MS Acute Exacerbation Fund, Defendants set up additional PAP funds with CDF. One such additional fund was the “RA Exacerbation Fund”. Again, the amount of the benefit was more than twice that of other funds at CDF, at least \$8,000 per patient, and the only drug treatment available under the fund was Acthar. Thus, Defendants replicated the success they had with the MS fund in other disease areas, including RA.



**THE QUI TAM WHISTLEBLOWER COMPLAINT AGAINST MALLINCKRODT**

422. On April 30, 2019, CNN reported that the United States Department of Justice (“DOJ”) had intervened in a false claims act action brought by two former employees of Mallinckrodt.

423. The intervention actually took place the month before, on March 6, 2019, but the case was sealed at the time. See Plaintiff Under Seal v. Defendant Under Seal, Civil Action No. 12-CV-0175-BMS, E.D.Pa., at Dkt. No. 55. The government’s decision to intervene, a relatively rare occurrence, was done after the government conducted its own extensive investigation of the claims by the former employees and concluded that the allegations are credible.

424. The case, now known as U.S. ex. Rel. Charles Strunck and Lisa Pratta, was filed in 2012 by Charles Strunck, New York-based former Multiple Sclerosis (“MS”) Sales Specialist for Questcor, and Lisa Pratta, a New Jersey-based Acthar neurology specialist for both Questcor and Mallinckrodt (collectively, the “Relators”). Strunck worked from September 2010 through August 2011, while Pratta worked from September 2010 through June 2017.

425. As reported by CNN, and as averred in their Qui Tam Complaint, the Relators allege that Mallinckrodt has engaged in a long-standing scheme to bribe doctors to prescribe Acthar at the exorbitant, inflated prices detailed herein. They claim there was a “culture” at Mallinckrodt designed to sell Acthar at all costs, from lying to the FDA to offering bribes to doctors.

426. Importantly, Mallinckrodt has not denied the allegations. Instead, Mallinckrodt claims the conduct alleged is a “legacy matter” involving Questcor and its conduct prior to Mallinckrodt’s acquisition.

427. However, Relator Pratta, who worked at both Questcor and Mallinckrodt after the 2014 acquisition, has alleged that the conduct continues at Mallinckrodt.

428. In a conference call with investors held May 7, 2019, CEO Mark Trudeau publicly stated that the company has reserved for the settlement of the Relators' case and is actively pursuing settlement which he stated is "likely to resolve sooner than later".

429. The conduct alleged by Relators involved kickbacks to doctors in the form of free Acthar, as well as active concealment by Mallinckrodt of the conduct for years.

430. For this reason, Local 420 did not know and could not have known about such unlawful conduct until the earliest date of April 30, 2019. As a result, Plaintiff's claims stated herein premised upon the unlawful conduct revealed by the Relators' case are timely.

431. Plaintiff had no way of knowing that Mallinckrodt was paying doctors thousands of dollars to prescribe Acthar to their patients.

432. The kickback scheme involved the promotion of Acthar to treat disease states for which Acthar was not the "gold standard", as in the case of IS, and for treatments that were not covered by the Acthar label.

433. For instance, Acthar is approved to treat acute exacerbations of disease. But the scheme uncovered by Relators involved widespread promotion of Acthar for the long-term treatment of disease as a maintenance medication.

434. Further, the scheme uncovered that Mallinckrodt sales representatives and MSLs were trained to promote unapproved doses of Acthar. For instance, in the treatment of MS exacerbations, Acthar is not approved by the FDA for 5-day dosing.

435. In the case of Local 420's beneficiary, the patient has been prescribed Acthar for years to treat a rheumatic disorder, not an RA exacerbation. As a result of Mallinckrodt's

promotional effort, instead of treating Local 420's beneficiary for an acute exacerbation, or flare-up, the patient has been given four prescriptions over the course of two months, forcing Local 420 to pay over one-hundred and fifty thousand dollars for Acthar.

436. In the case of IUOE Local 542, several beneficiaries have been treated by KOLs cultivated by Mallinckrodt to promote unapproved 5-day dosing for MS exacerbations. These prescriptions have cost IUOE Local 542 hundreds of thousands of dollars in expenditures for unapproved treatments which, in the case of Patient A, potentially put the patient at risk for a problem pregnancy.

437. The conduct revealed by the Relators goes to the manner in which Mallinckrodt was able to convince doctors to prescribe the high-priced Acthar, after the Defendant' conspired and agreed to raise the prices and maintain the prices at artificial levels, and to promote the sale of Acthar to such high prices through highly paid KOLs. The conduct involved systematically promoting and marketing Acthar for unapproved, off-label uses and doses, including the rheumatic disorder for which the Local 420 beneficiary has been prescribed Acthar.

438. The scheme involved compensating sales representatives thousands of dollars to promote the sale of Acthar for unapproved uses and doses, to benefit Mallinckrodt and the sales reps. Sales representatives have been paid tens of thousands of dollars for such promotional efforts. As detailed in the Relators' Qui Tam Complaint, one sales representative was paid a \$124,000 bonus in the second quarter of 2011, including \$75,000 for just one month. Others received bonuses of \$110,000 and \$80,000 in the same period.

439. The compensation of sales reps was directly tied to sales growth, a growth that was possible by expanding the approved uses for Acthar which had a narrow, limited market of patients.

440. Mallinckrodt employed a team of MSLs, like Sagar Shah, who were directed by Nikki Mutschler to join with sales specialists, like Strunck and Pratta to promote the sale of Acthar for unapproved uses. The Relators have identified the sales representatives who detailed the doctors of patients covered by IUOE Local 542, like Stacyann Clancy.

441. To hide the fact that the promotional effort was for unapproved, off-label uses, Mallinckrodt referred to such uses as “new indications.”

442. The sales of Acthar for these “new indications” became a primary focus for Mallinckrodt, as it strived to grow its revenue to the more than \$1 billion in sales it achieves each year for Acthar alone.

443. Mallinckrodt achieved such exponential growth, despite the price increases detailed herein, by providing valuable remunerations to doctors to induce and encourage them to prescribe Acthar for unapproved uses and doses.

444. As the Relators’ Qui Tam Complaint reveals, and as Local 420 alleges herein, Mallinckrodt engaged in such conduct in violation of the consumer fraud laws by providing secret kickbacks to doctors throughout the country, including Pennsylvania, to get them to prescribe Acthar at exorbitant prices, which Local 420 has been forced to pay. That is why Plaintiff seeks declaratory and injunctive relief against Mallinckrodt to end such practices.

### **CLASS ACTION ALLEGATIONS**

445. Local 420 brings this action pursuant to Rules 23(a), (b)(2) and (b)(3) of the Federal Rules of Civil Procedure, on behalf of itself and other similarly-situated persons and entities, and their beneficiaries, in Pennsylvania and throughout the country. The proposed Class includes:

All third-party payors and their beneficiaries in the United States and its Territories that paid for Acthar from August 2007 through

the present for any unapproved indication or dose.

446. Excluded from the above Class are: (a) Mallinckrodt and any entity in which Mallinckrodt has a controlling interest, and its legal representatives, offices, directors, assignees and successors, (b) any co-conspirators with Mallinckrodt, and (c) any government payor, including Medicare, Medicaid and/or Tricare.

Numerosity

447. The proposed Class consists of thousands of private payors in the proposed Class located throughout Pennsylvania and the United States, based on the fact that Mallinckrodt has sold thousands of vials of Acthar in each quarter over the last few years alone. Thus, the Class is so numerous that joinder of all of its members is impractical.

448. Despite the size of the Class, its members are easily identifiable and ascertainable, as each patient has been required by Mallinckrodt since 2007 to fill out an Acthar Start Form as part of the ASAP. As a result, the records needed to identify the members of the Class, and the payments made by TPPs and their beneficiaries in the Class, are in the hands of the Mallinckrodt and/or its agents.

Typicality

449. Local 420's claims are typical of the claims of the Class, in that the representative Plaintiff is an entity who, like other Class Members, paid for Acthar at the inflated prices due to the unlawful conduct of Mallinckrodt. Local 420, like all similarly-situated Class members, has been damaged and has sustained economic injuries in the form of overcharges by the misconduct of Mallinckrodt, because it paid higher prices than it would have paid absent Mallinckrodt's improper actions.

Adequacy of Representation

450. Local 420 can and will fairly and adequately represent and protect the interests of the Class. Plaintiff has no interest that conflicts with or is antagonistic to the interests of the Class.

451. Local 420 is represented by counsel who are experienced and competent in the prosecution of complex actions, including consumer fraud class actions.

Commonality

452. The factual and legal bases for Mallinckrodt's misconduct are common to Class members and represent a common thread of consumer fraud resulting in injury to Plaintiff and the Class. Common questions of law and fact in this case include, but are not limited to, the following:

- a. whether Mallinckrodt engaged in the unlawful marketing and sales scheme alleged;
- b. whether Mallinckrodt engaged physicians as "spoke-doctors" in the scheme involving KOLs alleged;
- c. whether Mallinckrodt artificially inflated the prices of Acthar;
- d. whether Plaintiff and the Class have been overcharged and thus damaged by paying artificially inflated prices for Acthar as a result of Mallinckrodt's unlawful conduct;
- e. whether Mallinckrodt engaged in the conduct involving PAPs and the payment of patients copays;
- f. whether Mallinckrodt engaged in conduct in violation of RICO;
- g. whether Mallinckrodt engaged in conduct in violation of the consumer fraud laws of Pennsylvania and other states;
- h. whether Mallinckrodt has been unjustly enriched by its unlawful conduct;
- i. whether Mallinckrodt negligently misrepresented Acthar to Plaintiff and the Class;

- j. whether Mallinckrodt engaged in a conspiracy and/or aided and abetted others in deceiving Plaintiff and the Class about Acthar and Acthar pricing, and concealing the truth about its unlawful conduct;
- k. whether Mallinckrodt is liable to Plaintiff and the Class for statutory damages for conduct actionable under the consumer fraud laws of Pennsylvania and other states;
- l. whether Plaintiff and members of the Class are entitled to declaratory and injunctive relief as to Mallinckrodt's conduct;
- m. whether Plaintiff and members of the Class are entitled to compensatory damages, and, if so, the nature of such damages;
- n. whether Plaintiff and members of the Class are entitled to statutory damages, including treble damages;
- o. the proper measure of damages; and
- p. whether Plaintiff and members of the Class are entitled to an award of punitive damages, reasonable attorneys' fees, prejudgment interest, post-judgment interest, costs of suit, and other appropriate relief under the circumstances of this case.

Predominance

453. These common questions of law and fact predominate over questions, if any, that may affect only individual members because Mallinckrodt has acted and refused to act on grounds generally applicable to the entire Class. Such generally applicable conduct is inherent in Mallinckrodt's unfair and deceptive conduct alleged herein.

Superiority

454. A class action is superior to any other available method for the fair and efficient adjudication of this controversy in that, among other things, such treatment will permit a large number of similarly-situated persons and entities to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of effort and expense that numerous individual actions would engender.

455. The prosecution of separate actions by individual members of the Plaintiff Class would create a risk of inconsistent or varying adjudications with respect to individual members of the Class. These adjudications would establish incompatible standards of conduct for Mallinckrodt which would, as a practical matter, be disparities of the claims of the other members not parties to the adjudications or substantially impair or impede their ability to protect their interests.

456. Mallinckrodt has acted or refused to act on grounds generally applicable to all members of the Class, thereby making appropriate final injunctive relief or corresponding declaratory relief with respect to the Class as a whole.

457. Accordingly, class certification is appropriate under Rule 23(b)(1)(A), 23(b)(1)(B), 23(b)(2) and 23(b)(3).

#### **FORMATION OF THE UNLAWFUL ACTHAR MARKETING ENTERPRISE**

458. Beginning in 2007 and continuing to the present, each Defendant implemented a marketing and promotion campaign by combining its own respective significant personnel and financial resources with peer-influencing physicians (known as KOLs) through which Defendants (i) falsely and deceptively oversold the safety and efficacy of Acthar, (ii) failed to adequately warn of, and affirmatively misled the medical community regarding the risks, benefits and value of Acthar and (iii) unlawfully promoted Acthar for usage in populations for which it had not received FDA approval and for which the safety and efficacy had not been established through adequate clinical evidence. This association-in-fact created by Defendants is denominated in this Complaint as the Acthar Marketing Enterprise. Defendants and their associated participants established the Acthar Marketing Enterprise to accomplish the common goal of causing increased prescribing activity of Mallinckrodt's Acthar for off-label uses and



doses for which Acthar was not proven to be safe, effective or useful. The scheme was accomplished through fraudulent, or false and deceptive, claims of efficacy and safety, medical usefulness, and for unlawful, off-label purposes.

459. First, to execute their Acthar Marketing Enterprise successfully, each Defendant had to create a parallel marketing structure that appeared independent from the ordinary promotion forces – they each did so both to avoid federal regulations concerning off-label promotion and to create the façade of independence behind the misleading message of safety, efficacy and non-indicated usage they each wished to promote. Defendants targeted primarily speaking events, seminars, continuing medical education (“CME”) events as well as other physician gatherings. Defendants worked with and paid leading KOLS to create content for such speaking events that misrepresented the safety, efficacy, and usefulness of Acthar for off-label uses, and paid these KOLs to deliver the disguised promotional messages to unsuspecting physician attendees.

460. The goal of the Acthar Marketing Enterprise was intentionally complementary and mutually reinforcing. The Defendants’ Acthar Marketing Enterprise was succeeded in distorting and polluting the medical discourse and medical literature surrounding Acthar to such a degree that physicians and patients were rendered incapable of making objective and informed decisions concerning the appropriateness of Acthar for off-label and label-expanding usage.

**A. FORMATION OF THE ILLEGAL ACTHAR MARKETING ENTERPRISE**

461. Defendants’ Acthar Marketing Enterprise centered on hosting numerous events where KOL doctors rained and/or approved by Defendants would falsely oversell the efficacy and safety of Acthar and would provide favorable information on the off-label use of Acthar, often under conditions where physicians would be compensated for attending the presentation.

Mallinckrodt funded and continues to fund scores of such events between approximately 2007 to present.

462. The Acthar Marketing Enterprise employed improper and unlawful sales and marketing practices, including: (a) deliberately misrepresenting the safety and medical efficacy of Acthar for a variety of off-label uses; including 5-day dosing for MS exacerbations; (b) knowingly misrepresenting the existence and findings of scientific data, studies, reports and clinical trials concerning the safety and medical efficacy of Acthar for both approved indications and for a variety of off-label uses and doses; (c) deliberately concealing negative findings or the absence of positive findings relating to the off-label uses of Acthar; (d) wrongfully and illegally compensating physicians for causing the prescribing of Acthar; (e) knowingly publishing articles, studies and reports misrepresenting the scientific credibility of data and touting the medical efficacy of Acthar for both on-label and off-label uses, and then disseminating copies of such studies by the thousands to the medical community as part of their marketing; (f) intentionally misrepresenting and concealing Defendants' role and participation in the creation and sponsorship of a variety of events, articles and publications used to sell Acthar to off-label markets; and (g) intentionally misrepresenting and concealing the financial ties between Defendants and other participants in the Acthar Marketing Enterprise.

463. Defendants' scheme reaped significant financial gain. From 2007 to present, Defendants revenues from the sale of Acthar soared into the millions and billions of dollars. Eventually, as a result of each Defendants' Acthar Marketing Enterprise efforts and unbeknownst to the Plaintiff and Class Member TPPS, the vast majority of Acthar prescriptions were for off-label uses. Sales of each drug have grown at a significant rate each year. Currently, Acthar represents over \$1 billion in revenue to Mallinckrodt.

464. All of the participants in Defendants Acthar Marketing Enterprise associated with the respective Defendants with the common purpose of aiding them in marketing Acthar for off-label uses and to achieve “market expansion” of these uses. Each of the participants received substantial revenue or other consideration from each Defendant for their efforts in the scheme to promote Acthar off-label. The more successful these marketing events were, the more events there would be in the future and the more fees and revenues each of the participants would receive for participating in the events. For these reasons, all of the participants knowingly and willingly agreed to assist each of the Defendants in their off-label promotion of Acthar, notwithstanding the fact that such a promotional campaign required the systematic repetition of false and misleading statements to, and the commercial bribery (through kickbacks) of hundreds of physicians throughout Pennsylvania and the United States, and that the promotion of Acthar for off-label indications by Defendants was illegal.

465. Each Defendant exercised control over and participated in the Acthar Marketing Enterprise. Each Defendant compensated the other participants for their efforts, and controlled the money flow to the participating physicians. Defendants each closely monitored all activities and events to ensure the expected representations and marketing messages related to the off-label uses of Acthar were made to physicians attending the events. Following the events, each Defendant tracked attending physicians’ prescribing habits to ensure that the messaging was successful in causing prescribing activity for Acthar.

**1. Role of Physicians in the Acthar Marketing Enterprise.**

466. One of the principal strategies pursued by all Defendants in their Acthar marketing Enterprise was to target key physicians to serve as “thought leaders”, or KOLs. These doctors promoted Acthar to their peers through peer selling programs by (i) touting Acthar’s

supposed off-label uses; (ii) claiming that Acthar was being widely used by other physicians for off-label uses; and (iii) claiming that they were privy to the latest clinical data that had not been released yet, but which would support off-label use.

467. To lure physicians to participate in the Acthar Marketing Enterprise, Mallinckrodt sales representatives and MSLs approached target doctors and informed them of an interest in funding research opportunities and clinical trials at their practices and institutions. Doctors who were willing to speak favorable about Acthar could receive substantial funds in the form of research grants or other monies. In addition, these doctors were frequently remunerated for other less-defined services, including “consulting” and “advisory board” services. Mallinckrodt instructed its sales department to select doctors at the major teaching hospitals to become Acthar “experts” and KOLs who would in turn deliver the Acthar message to other physicians to grow sales. This was done formally to other physicians at marketing events or informally to colleagues within a hospital or medical practice, or at a dinner or lunch roundtable.

468. Having recruited these physicians, Defendants’ Acthar Marketing Enterprise created an explosion in the off-label use of Acthar by artificially creating the perception that physician specialists were clinically using Acthar and investigating with positive results their efficacy in off-label uses on their own initiative, and not as a result of the illegal marketing activities and inducements. Mallinckrodt developed a stable of physicians to create this perception. Mallinckrodt paid these physicians to induce them to write PA denial appeals, letters to the editor and other documents that favorably discussed the off-label use of Acthar. Mallinckrodt also paid these physicians (in addition to providing free travel to resorts, free lodging and free meals) to induce them to give talks at medical education seminars, advisory boards, consultants’ meetings, speakers bureaus and similar events where the primary focus of

the discussion was the off-label use of Acthar. The physicians who accepted these benefits and agreed to promote Acthar off-label to other doctors were physician participants in the Defendants' Acthar Marketing Enterprise. The individual physician participants received tens of thousands of dollars, and in some cases hundreds of thousands, to promote the off-label uses of Acthar. Participation in the Enterprise through sham "authorships" and serving as presenting "faculty" at CME events and other honoraria also enhanced the physician participants' professional reputations.

469. The return on investment ("ROI") in Defendants' Marketing Enterprise was highly favorable.

470. Physician participants were absolutely critical to the success of Defendants' Acthar Marketing Enterprise. Indeed, the marketing plans drafted by Mallinckrodt required their participation. The participation of physicians allowed Mallinckrodt to disguise promotional events as educational events or consultants' meetings. Moreover, as noted above, Mallinckrodt and UBC knew that peer-to-peer selling was far more persuasive than traditional drug rep detailing.<sup>12</sup> Primary care physicians are more likely to follow the advice of a Professor of Medicine at Johns Hopkins or another teaching hospital than that of a sales rep. By funneling the payments to physician participants through the vendor participants, the Acthar Marketing Enterprise could hide the speakers' financial ties with Defendants, and the Enterprise was able to mislead the physician-listeners into believing that the speakers were not biased and that the events were not promotional. As a result, the vast amounts of money the participating physicians

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<sup>12</sup> When a sales representative "details" a physician, often during a call to the physicians' office during work hours, the representative delivers to the physician the pharmaceutical company's key selling messages for one or more pharmaceutical products. In some cases, the sales pitch is accompanied by handing out free samples of the product and/or approved materials delivered to the physician, such as sales aids, slides or branded merchandise such as pens and prescription pads. Here, Defendants were able to steer physicians through ASAP to UBC for PAP.

received from the Defendants, for speaking and other purposes, was largely hidden from the physicians who attended events at which the participating physicians spoke.

471. Physicians who participated in the Acthar Marketing Enterprise either as speakers or as authors, entered into mutually advantageous contractual relationships with Mallinckrodt. The more favorable a physician's statements were, the more he or she could expect to receive in the form of speaker fees, consulting fees, advisory board fees, and research grants. Physicians who refused to deliver the favorable off-label message that Mallinckrodt wanted were blackballed and would not receive additional payments.

472. The participating physicians knew that minimal scientific evidence supported the use of Acthar for the off-label uses and that the type of clinical evidence that existed was insufficient, under the accepted standards in the medical profession, to represent that Acthar worked for the unapproved indications.

473. All of the physician participants had personal relationships with employees of Defendants, whether the Mallinckrodt sales reps and MSLs, or the UBC RSs, and frequently Mallinckrodt recommended specific individual participants for event.

474. Plaintiff does not at this time know the identity of all of the physician participants, which likely number in the hundreds.

475. The Defendants' Acthar Marketing Enterprise sponsored hundreds of events across the country between 2007 and the present. Through Propublica, the Plaintiff is only able to identify physicians by payments, including travel, food, lodging and entertainment benefits they received for events held at resorts or out of town hotels.

476. In order to implement their respective plans to transform Acthar into the blockbuster drug it has become, despite a small on-label patient population, Acthar created a

separate Acthar Marketing Enterprise composed of each Defendant, and dozens of physician participants, some of whom are listed above and others whose identities will be revealed in discovery. These participants all acted together and under each Defendants' control in promoting Acthar's off-label to the healthcare industry, employing numerous tactics with an enormous degree of success.

477. Mallinckrodt hosted numerous seminars and events over the course of several years that were falsely represented to be neutral, educational forums. At these events, the roster of physician participants provided misleading and deceptive information to fellow physicians on the off-label uses of Acthar (i.e. peer-to-peer marketing). The physician participants were not independent, but received behind-the-scenes coaching and remuneration from Mallinckrodt and/or its vendors, and often used slide decks and PowerPoint presentations prepared by the marketing teams of Mallinckrodt Targeted audience members, many of whom were primary care physicians or specialists in MS, NS and RA, were not aware that the specialists (including prominent neurologist and nephrologists) speaking to them were in fact delivering, and being paid to deliver, the off-label marketing message of Mallinckrodt.

478. In addition, the sales force of Mallinckrodt promoted Acthar to physicians through "details" or sales calls to physicians' offices. On these sales calls, sales representatives often using a sales aid and/or sales script developed by Mallinckrodt "detail" the physician on the off-label uses of Acthar. In addition, the sales representatives were instructed to deliver to physicians reprints of medical journal articles advocating the off-label use of Acthar, many of which were created by the KOLs paid by Mallinckrodt, and to notify physicians of and ask for their attendance at upcoming CME events and lectures sponsored by Mallinckrodt pursuant to



the Acthar Marketing Enterprise. All aspects of each Defendants' Acthar Marketing Enterprise were mutually reinforcing.

479. All components of each Defendants' Acthar Marketing Enterprise were fully integrated and operated under each Defendants' exclusive control, through the ASAP program.

**DEFENDANTS' USE OF THE MAILS AND WIRES TO CREATE AND MANAGE  
THEIR FRAUDULENT SCHEME**

480. Defendants used, and knowingly caused the use of, mail and interstate wire communications to create, execute, and manage their fraudulent schemes, as well as to further them. This scheme involved the national marketing and sale plan that comprised ASAP, and encompassed physicians and consumers across the country.

481. Defendants' use of, and causing the use of, the mails and wires in furtherance of their schemes to defraud involved thousands of communications and transmission through the Class period all over the country, including:

- Transmission through mail and wire marketing and advertising materials about the off-label uses of Acthar to and from physicians across the country, including and especially the Acthar Start Forms which were faxed to UBC;
- Communications and transmissions, including financial payments, from Defendants or vendors to participants in the Acthar Marketing Enterprise, including physicians, discussing and relating to the production and publication of articles and dissemination of materials misrepresenting the off-label uses and safety and efficacy of Acthar.
- Communications with Plaintiff and the Class Members and their beneficiaries, other health insurers, and patients, including payments for Acthar to be made based on misrepresentations concerning their safety, efficacy, effectiveness, and usefulness; and
- Communications, payments and monetary transfers using the wires concerning the receipt and distribution of the proceeds of Defendants' improper scheme.

482. In addition, Defendants' respective corporate headquarters have communicated, and knowingly cause communications, by United States mail, telephone and facsimile with or by



various local district managers, MSLs, RSs and pharmaceutical sales representatives, in furtherance of Defendants' scheme.

**COUNT I**  
**VIOLATION OF 18 U.S.C. § 1962(C)**

483. Plaintiff hereby incorporates by reference the averments of the foregoing paragraphs as if fully set forth herein and further alleges as follows:

484. Defendants are each "persons" within the meaning of 18 U.S.C. § 1961(3), who each conducted the affairs of the Acthar Marketing Enterprise through a pattern of racketeering activity in violation of 18 U.S.C. § 1962(c). Plaintiff and the members of the Class are also persons.

485. The Acthar Marketing Enterprise is an association in fact enterprise affecting interstate commerce within the meaning of 18 U.S.C. § 1961(4) consisting of (i) Mallinckrodt, and its MSLs and sales representatives, (ii) UBC, and its RSs, and (iii) KOLs, both named and unnamed in this Complaint. At all relevant times, in violation of 18 U.S.C. § 1962(c), Mallinckrodt, UBC, the KOLs and other co-conspirators conducted the affairs of an association-in-fact enterprise within the meaning of 18 U.S.C. § 1961(4), including their directors, employees, and agents who assisted in carrying out their alleged scheme.

486. The Acthar Marketing Enterprise falls within the meaning of 18 U.S.C. § 1961(4) and consists of a group of "persons" associated together for the common purpose of promoting Acthar for off-label uses and doses and earning profits therefrom.

487. Mallinckrodt and UBC have conducted and participated in the affairs of the Acthar Marketing Enterprise through a pattern of racketeering activity within the meaning of 18 U.S.C. §§ 1961(1) and 1961(5), which includes multiple instances of mail fraud in violation of 18 U.S.C. § 1341, and multiple instances of wire fraud in violation of 18 U.S.C. § 1343, as

described above. The unlawful predicate acts of racketeering activity committed, or caused to be committed, by Mallinckrodt and UBC throughout the Class Period number in the thousands, and Mallinckrodt and UBC committed, or caused to be committed, at least two of the predicate acts within the requisite ten (10) year period, a period which began in 2007 and continues through the present.

488. This enterprise was manifested by and through the ASAP program, but was made up of the three components of the alleged scheme: the Distribution Scheme, the Pricing Scheme and the Marketing Scheme. Accordingly, the enterprise concerned the marketing and sale of Acthar pursuant to the 2007 new strategy with each of these components described herein.

489. The Acthar Marketing Enterprise was begun in 2007, and is an ongoing and continuing business organization consisting of both corporations (*i.e.*, Mallinckrodt and UBC) and individuals (*s* MSLs, RSs, KOLs), associated for the common purpose of distributing, pricing and marketing Acthar to Plaintiff and the Class at exorbitant AWP prices, and deriving substantial profits from these activities.

490. The Acthar Marketing Enterprise engages in and affects interstate commerce because it engages in the following activities across state boundaries: the distribution, pricing, marketing, sale, and/or purchase of Acthar, the transmission of WAC and AWP pricing information to the pricing compendia, ASAP program literature (including the Acthar Start Form at Exhibit “A” hereto), the operating of the ASAP program website, communications with providers, patients and TPPs by UBC as part of ASAP, and the transmission and/or the receipt of invoices and payments related to the prescription and use of Acthar. Through these activities the Acthar Enterprise markets, distributes and sells Acthar to thousands of individual patients, including those receiving prescription drug benefits from the Plaintiff and the Class.

491. The Acthar Marketing Enterprise has functioned as a continuing unit, as evidenced by the continuing coordination of activities between Mallinckrodt and UBC. There is a common communication network by which Mallinckrodt and UBC (and their agents and employees, including MSLs, RSs and KOLs) shared and continue to share information on a regular basis for all times relevant to this lawsuit, but beginning at least in 2007 and continuing through the present. Typically, this communication occurred by use of the wires and mails, in which Mallinckrodt, UBC and KOLs all agree to charge TPPs inflated AWP prices for Acthar to the patients of TPPs, like Local 420, and other Class members. These entities functioned as a continuing unit for the purposes of implementing the scheme to inflate the prices of Acthar by and through ASAP. When issues arose during the scheme, each agreed to take actions to hide the scheme and to continue its existence.

492. Defendants have exerted control over the Acthar Enterprise, have associations with the Enterprise, and have directly or indirectly conducted or participated in the conduct of the affairs of the ASAP Enterprise in the following ways:

- a. Defendants have directly controlled the AWP price at which Plaintiff and the Class purchase Acthar;
- b. Defendants have directly controlled the AWP price at which Plaintiff and the Class reimburse for Acthar;
- c. Defendants have directly controlled the ASAP program materials and website which enroll patients in an exclusive distribution network for the administration of Acthar, allowing Mallinckrodt and UBC to conduct their unconscionable and unfair pricing of Acthar;
- d. Defendants have directly controlled the exclusive distribution network for Acthar through the ASAP Enterprise;
- e. Defendants have relied on their employees to promote the ASAP program through the marketing alleged herein, through the mail and the wires;

- f. Defendants placed their own employees and agents in positions of authority and control over the Acthar Marketing Enterprise;
- g. Defendants controlled the content of the messages being delivered by the Acthar Marketing Enterprise at each seminar, event, and presentation, in the publications being used and presented, in the direct communications with providers, patients and payors, all of which included misinformation and false and misleading statements about the safety, efficacy, effectiveness, usefulness, and value of Acthar for off-label uses;
- h. Defendants have participated in the affairs of the ASAP Enterprise by using a fraudulent scheme to market and sell Acthar at inflated prices;
- i. Mallinckrodt has selected and approved physicians to serve as KOLs, who in turn work with UBC under the ASAP to deliver off-label prescriptions of Acthar for payment by TPPs; and
- j. Defendants worked to ensure that the Acthar prescribed by KOLs and other providers were paid for by TPPs at the inflated AWP's charged by them.

493. Defendants have conducted and participated in the affairs of the ASAP Enterprise through a pattern of racketeering activity that includes acts indictable under 18 U.S.C. § 1341, relating to mail fraud, and 18 U.S.C. § 1345, relating to wire fraud. Defendants' pattern of racketeering activity likely involved hundreds, if not thousands, of separate instances of the use of the United States mail, private shipping services, facsimiles, or interstate wires, including the internet, in furtherance of its fraudulent and unlawful scheme. Each of these fraudulent mailing and interstate wire transmissions separately constitutes a "racketeering activity" within the meaning of 18 U.S.C. § 1961(1). Collectively, these violations constitute a "pattern of racketeering activity" within the meaning of 18 U.S.C. § 1961(5) in which the Defendants intended to defraud Plaintiff and members of the Class.

494. As described in greater detail herein, Defendants' fraudulent scheme consisted of confining patients to an exclusive distribution network, such that they could drastically inflate the prices charged for Acthar. By conducting this program through the mail and wires,

Defendants engaged in a repeated, fraudulent, and unlawful course of conduct constituting a pattern of racketeering.

495. As detailed above, the Acthar Marketing Enterprise consisted of: (a) deliberately misrepresenting, and causing others to misrepresent, the uses for which Acthar was safe and effective so the Plaintiff and the Class Members paid for this drug at inflated prices to treat conditions and/or symptoms for which it was not scientifically proven to be safe, effective, useful and valuable; (b) presenting seminars, events, in-person meetings and telephonic communications misrepresenting the off-label uses of Acthar for which Defendants knew Acthar was not proven to be scientifically safe, effective, useful or valuable to physicians and other healthcare providers; (c) disseminating materials created pursuant to the Acthar Marketing Enterprise and using those materials to misrepresent, and cause others to misrepresent, the uses for which Acthar was safe, effective, useful and valuable; and (d) actively concealing, and causing others to conceal, information about the safety, efficacy, usefulness and value of Acthar to treat conditions for which it had not been approved by the FDA.

496. These racketeering activities amounted to a continuing course of conduct, with similar pattern and purpose, intended to harm Plaintiff and the Class to pay excessive amounts for Acthar. Each instance of racketeering activity perpetuated by the Defendants was related, and had a similar intended purpose, involved similar participants and methods of execution, and have the same results affecting the same class of victims, including Plaintiff and the Class. Defendants had engaged in this pattern of racketeering activity for the purpose of conducting the ongoing business affairs of the Acthar Marketing Enterprise.

497. Defendants' pattern of racketeering activities alleged herein are separate and distinct from each other.

498. Defendants' pattern of racketeering activities had directly and proximately caused Plaintiff and members of the Class to be injured in their property insofar as Plaintiff and members of the Class have overpaid thousands of dollars in inflated reimbursements and other payments for Acthar. Plaintiff's and the Class Members' injuries were directly caused by the predicate acts and are not attributable to any independent or intervening forces; their injuries were a foreseeable and natural consequence of the Defendants' scheme; there is no difficulty posed by having to apportion damages among Class Members with potentially different standing or levels of injury because there are no other injured parties besides Plaintiff and the TPP Class Members in this case, who are the parties directly injured by the Defendants' RICO violations. No one other than Plaintiff and the Class could vindicate the rights and claims of Plaintiff and the Class.

499. By virtue of these violations of 18 U.S.C. § 1962(c), Defendants are jointly and severally liable to Plaintiff and the Class for three times the damages Plaintiff and the Class have sustained, plus the costs of this suit, including reasonable attorney's fees.

**COUNT II**  
**CONSPIRING TO VIOLATE 18 U.S.C. § 1962(c)**  
**(18 U.S.C. § 1962(d))**

500. Plaintiff hereby incorporates by reference the preceding and following paragraphs hereof as if fully set forth herein and further allege as follows.

501. Section 1962(d) of RICO provides that it "shall be unlawful for any person to conspire to violate any of the provisions of subsection (a), (b), or (c) of this section." 18 USC § 1962(d).

502. Defendants violated section 1962(d) by conspiring to associate with a racketeering enterprise, in violation of 18 U.S.C. § 1962(c). Mallinckrodt knowingly joined

UBC and others in a conspiracy to inflate the prices of Acthar and marketing the off-label uses and doses of Acthar in violation of § 1962(c).

503. The object of this conspiracy is to and has been to conduct or participate in, directly or indirectly, the conduct of the affairs of the Acthar Marketing Enterprise described herein, through a pattern of racketeering activity that directly cause injury to the business or property of Plaintiff and the Class within the meaning of 18 U.S.C. § 1964(c). The corporate defendants conspired with, inter alia, the sales representatives, MSLs, RSs, KOLs and others to promote Acthar and suppress information about the harms known to result from Acthar use.

504. Defendants and their co-conspirators have engaged in numerous overt and predicate fraudulent racketeering activities in furtherance of the conspiracy, including material misrepresentations and omissions designed to defraud Plaintiff and the Class of money.

505. That Mallinckrodt knew and adopted the criminal purpose of the Enterprise is evident from its own documents and public statements of its officers. Mallinckrodt communications reflect an express illegal agreement between Mallinckrodt and UBC to form and operate the ASAP in furtherance of the Acthar Marketing Enterprise. Mallinckrodt's officers stated that it was this agreement in 2007 that was the hallmark of a new strategy to increase revenues and profits.

506. The nature of the above-described AbbVie Defendants' co-conspirators' acts, material misrepresentations, and omissions in furtherance of the conspiracies gives rise to an inference that they not only agreed to the objective of an 18 U.S.C. § 1962(d) violation of RICO by conspiring to violate 18 U.S.C. § 1962(c), but they were aware that their ongoing fraudulent acts have been and are part of an overall pattern of racketeering activity. In other words, the



Defendants adopted the goal of furthering or facilitating the conspiracy, and were aware of the essential nature and scope of the Acthar Marketing Enterprise and intended to participate in it.

507. Additionally, Defendants' conduct in sending e-mails, faxes and other communications to each other to direct the distribution and sale of Acthar through ASAP is consistent with the existence of an agreement to carry out the scheme to inflate prices and maximize profits.

508. Defendants actively furthered the goals of the Acthar Marketing Enterprise to defraud end payors, like Plaintiff. They changed the distribution scheme for Acthar with the intention that the changes would allow the Pricing Scheme to be effectuated; engaged in frequent discussions with between each other about the plan to raise Acthar prices and to promote the sale of Acthar at these new high prices for unapproved uses and doses in the marketplace; and communicated with KOLs and other providers about the same.

509. The Defendants sought to and have engaged in the commission of and continue to commit overt acts, including the following unlawful racketeering predicate acts: a) multiple instances of mail and wire fraud violations of 18 U.S.C. §§ 1341 and 1342; b) multiple instances of mail fraud violation of 18 U.S.C §§ 1341 and 1346; c) multiple instances of wire fraud violations of 18 U.S.C. §§ 1341 and 1346; and d) multiple instances of unlawful activity in violation of 18 U.S.C. § 1952.

510. The Defendants' violations of the above federal laws and the effects thereof detailed above are continuing and will continue.

511. Plaintiff and members of the Class have been injured in their property by reason of these violations in that Plaintiff and members of the Class have paid millions of dollars in



overpayments for Acthar that they would not have paid had the Defendants not conspired to violate 18 U.S.C. § 1962(c).

512. Injuries suffered by Plaintiff and members of the Class were directly and proximately caused by the Defendants' racketeering activity as described above. As also set forth above, these injuries would not have occurred but for the Defendants' RICO predicate act violations, and they involved concrete financial losses to the Plaintiff and the Class Members.

513. Patients, physicians, and TPPs, including Plaintiff and the Class, directly relied on the racketeering activities of the Defendants' and the Acthar Marketing Enterprise. Plaintiff and the Class Members, both directly and indirectly, relied on the representations as to the necessity, approval and safety of Acthar as promoted by the Defendants. Because the Defendants controlled all knowledge upon which the claims of Acthar's necessity, approval and safety were based, all Class Members, as well as other members of the medical and consuming public were obligated to rely on the Defendants' representations about Acthar. Further, the Defendants perpetuated this reliance by taking the steps itemized above to suppress the dissemination of any critical information about Acthar.

514. As co-conspirators, Mallinckrodt and UBC are jointly and severally liable for all damage that occurred as a result of both their actions in furtherance of the conspiracy to raise prices of Acthar and market the sale of Acthar at inflated prices for unapproved uses and doses. Mallinckrodt is liable for all damages arising from UBC's conduct in furtherance of the scheme, as it UBC liable for all damages from Mallinckrodt's conduct in furtherance of the scheme.

515. By virtue of these violations of 18 U.S.C. § 1962(d), the Defendants are liable to Plaintiff and the Class Members for three times the damages Plaintiff and the Class Members have sustained, plus the cost of this suit, including reasonable attorneys' fees.

516. By reason of the foregoing, and as a direct and proximate result of the Defendants' fraudulent misrepresentations, Plaintiff and the Class Members have suffered damages. Plaintiff and the Class Members are entitled to compensatory damages, equitable and declaratory relief, punitive damages, costs and reasonable attorneys' fees.

517. By reason of the foregoing, Plaintiff and the Class Members have been damaged as against the Defendants in a sum that exceeds the jurisdiction of all lower courts.

**COUNT III**  
**PENNSYLVANIA UNFAIR TRADE PRACTICES AND**  
**CONSUMER PROTECTION LAW**

518. Plaintiff hereby incorporates by reference the preceding and following averments as if fully set forth herein and further alleges as follows.

519. Pennsylvania's Unfair Trade Practices and Consumer Protection Law, 73 Pa. Stat. Ann. §§201, et seq. ("UTPCPL") makes unlawful any "unfair methods of competition" and "unfair or deceptive acts or practices", including the following, among others:

(ii) Causing likelihood of confusion or of misunderstanding as to the source, sponsorship, approval or certification of goods or services;

(v) Representing that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits or quantities that they do not have or that a person has a sponsorship, approval, status, affiliation or connection that he does not have;

(vii) Representing that goods or services are of a particular standard, quality or grade, or that goods are of a particular style or model, if they are of another;

(viii) Disparaging the goods, services or business of another by false or misleading representations of fact;

(xi) Making false or misleading statements of fact concerning the reasons for, existence of, or amounts of price reductions; and

(xxi) Engaging in any other fraudulent or deceptive conduct which creates a likelihood of confusion or of misunderstanding.

520. The unfair methods of competition, and unfair or deceptive acts or practices, in the conduct of any trade or commerce as defined above are declared unlawful under the UTPCPL.

521. Defendants engaged in the following unfair and deceptive acts or practices, which violate the aforesaid provisions of the UTPCPL:

- a. By entering into the exclusive distribution arrangement described herein in 2007, and not disclosing the same to Local 420, Mallinckrodt and UBC engaged in deceptive acts and made misrepresentations to Plaintiff and its beneficiary that impeded Plaintiff's efforts to contain costs for specialty drugs like Acthar. By then sending (or causing to be sent) bills for Acthar which charged the artificially inflated prices, and by communicating directly with patients about the misleading messages described above, Mallinckrodt injured Plaintiff and the Class. This caused at least a likelihood of confusion or of misunderstanding as to the source, sponsorship, approval and/or certification of Acthar sold by Mallinckrodt, misrepresented the same, and/or constituted fraudulent or deceptive conduct which created a likelihood of confusion or a misunderstanding by Plaintiff.
- b. Defendants conspired and agreed to adopt the above-described ASAP program and the Acthar Start Form in 2007, and to maintain and use the ASAP and Acthar Start Form through 2018 (when Plaintiff paid for Acthar), in order to mislead and deceive Local 420 and its beneficiary about the Mallinckrodt "hub" of patient care at UBC as it concerns the new conditions for which Acthar is not indicated, and to bypass Plaintiff's efforts to contain and reduce costs for specialty drugs, especially for new indications.
- c. Starting in July 2007, Mallinckrodt issued a misleading and deceptive announcement about its new distribution strategy, but the announcement failed to disclose that all aspects of Acthar distribution, pricing and product sales were now being coordinated through UBC as part of a "hub" of services for which Mallinckrodt contracted.
- d. Mallinckrodt and UBC misled and deceived Local 420 in the decision to raise the prices of Acthar, and the lack of value of Acthar for the prices being charged, in order to intentionally and

deceptively charge false, misleading and excessive prices for Acthar, during the period between 2007 (when Mallinckrodt adopted its “new strategy” they entered into their exclusive distribution and hub arrangement), through 2018 (when Local 420 began to pay for Acthar). Mallinckrodt then falsely claimed to offer discounts off the inflated prices of Acthar, thereby misleading Plaintiff as to the reasons for, existence of, or amounts of the Acthar price reductions, in violation of sub-section (xi).

- e. Defendants acts or practices, including the failures to act and to speak the truth in the face of false, misleading and deceptive statements about Acthar’s pricing, distribution and value, constitute “other fraudulent or deceptive conduct which creates a likelihood of confusion or of misunderstanding, in violation of sub-section (xxi).

522. The UTPCPL authorizes any person, including natural persons, corporations, trusts, partnerships, incorporated and unincorporated associations, and any other legal entities to seek an injunction, damages, costs, and reasonable attorneys’ fees to prevent and ameliorate the anticompetitive conducted described herein.

523. Local 420 is a person pursuant to the UTPCPL. Local 420 has been injured as a result of the Defendants’ conduct in violation of Pennsylvania law, by virtue of having paid for Acthar in Pennsylvania, and hereby seeks damages. Plaintiff has purchased or reimbursed the costs of multiple administrations of Acthar distributed by Defendants to Local 420 ’s beneficiary for her personal, family or household use and purpose. Because Local 420’s beneficiary paid only a minimal co-pay (\$70), Local 420 paid the bulk of the inflated prices of Acthar to Mallinckrodt.

524. The acts and practices described herein demonstrate that Mallinckrodt acted unlawfully within the meaning of the UTPCPL such that Local 420 may be awarded up to three times its actual damages sustained, and such additional relief as deemed necessary or proper. These damages consist of, inter alia, the difference between the true price of Acthar, before

Mallinckrodt began in 2007 to artificially inflate the “average wholesale price” of Acthar, and the inflated prices of Acthar charged to Plaintiff in 2018. The damages of the Class may be calculated in the same manner.

525. Local 420 seeks relief against Mallinckrodt for its unfair and deceptive conduct which allowed it to raise and fix the prices of Acthar at supra-competitive levels.

526. Local 420 was injured as a direct result of Mallinckrodt’s conduct in violation of the UTPCPL sections above, and hereby seeks damages.

**WHEREFORE**, Steamfitters Local Union No. 420 demands that judgment be entered in its favor and against Defendants in an amount to be determined at trial, including but not limited to costs, attorneys’ fees, and such other relief deemed just and appropriate by this Court.

**COUNT IV**  
**DEFENDANTS’ VIOLATIONS OF OTHER STATE**  
**CONSUMER PROTECTION LAWS**

527. Plaintiff hereby incorporates by reference the preceding and following averments as if fully set forth herein and further alleges as follows:

528. Mallinckrodt violated the consumer protection laws of all other states by engaging in unfair methods of competition and unfair deceptive acts and practices as described herein. Plaintiff brings claims under the laws of these states on behalf of the consumer purchasers of Acthar in such states. Excluded from this case are the states of Iowa which do not allow consumers to sue. Plaintiff does not seek class certification of consumer fraud claims under the laws of Alabama, Georgia, Mississippi, and South Carolina, as those state laws do not permit class actions. However, the individual claims of consumers in those states should be permitted to be advanced in this lawsuit to benefit from those this Court’s rulings on Mallinckrodt’s conduct, especially as to the declaratory and injunctive relief sought by the Plaintiff.

**Alabama’s Deceptive Trade Practices Act (“Alabama DTPA”)  
Ala. Code §§ 8-19-1, *et seq.***

529. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of Alabama’s Deceptive Trade Practices Act, Ala. Code § 8-19-1, *et seq.*

530. Alabama Code § 8-19-5(27) declares that “[e]ngaging in any other unconscionable, false, misleading, or deceptive act or practice in the conduct of trade or commerce” is unlawful.

531. The unconscionable, unfair and deceptive acts and practices described herein are declared unlawful under the Alabama DTPA.

532. The DTPA authorizes any person, including “a natural person, corporation, ... ” to seek an injunction, damages, costs, and reasonable attorneys’ fees to prevent and remedy the unfair and deceptive conduct described herein.

533. Mallinckrodt marketed and sold Acthar in Alabama pursuant to the marketing and sales scheme alleged, at the inflated prices set forth herein.

534. Members of Plaintiff Class who purchased and/or reimbursed the cost of Acthar at these inflated prices in Alabama are persons under the DTPA. Each has been injured as a direct and proximate result of Mallinckrodt’s unconscionable, unfair, and deceptive conduct in violation of the DTPA, and each hereby seeks damages, through their representative Local 420.

**Alaska’s Unfair Trade Practices and Consumer Protection Act (“UTPCPA”) Alaska  
Stat. §§ 45.50.471, *et seq.***

535. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of Alaska’s Unfair Trade Practices and Consumer Protection Act, Alaska Stat. § 45.50.471, *et seq.*

536. Alaska Statute 45.50.471(a) declares that “[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of trade or commerce” are unlawful. Alaska Statute 45.50.471(b)(12) provides that the terms “unfair methods of competition” and “unfair or deceptive acts or practices” include using or employing deception, fraud, false pretense, false promise, misrepresentation, or knowingly concealing, suppressing, or omitting a material fact with intent that others rely upon the concealment, suppression or omission in connection with the sale or advertisement of goods or services, whether or not a person has in fact been misled, deceived or damaged.

537. The unconscionable, unfair and deceptive acts and practices described herein are declared unlawful under the Alaska UTPCPA.

538. The UTPCPA authorizes any person, including “a natural person, corporation, ...” to seek an injunction, damages, costs, and reasonable attorneys’ fees to prevent and remedy the unfair and deceptive conduct described herein.

539. Mallinckrodt marketed and sold Acthar in Alaska pursuant to the marketing and sales scheme alleged, at the inflated prices set forth herein.

540. Members of Plaintiff Class who purchased and/or reimbursed the cost of Acthar at these inflated prices in Alaska are persons under the UTPCPA. Each has been injured as a direct and proximate result of Mallinckrodt’s unconscionable, unfair, and deceptive conduct in violation of the UTPCPA, and each hereby seeks damages, through their representative Local 420.

**Arizona Consumer Fraud Act (“Arizona CFA”)  
Ariz. Rev. Stat. § 44-1522, *et seq.***

541. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of the Arizona CFA, Ariz. Rev. Stat. § 44-1522, *et seq.*



542. The Arizona CFA is a broadly drafted remedial provision designed to eliminate unlawful practices in merchant-consumer transactions.

543. By the Arizona CFA, an unlawful practice is defined as follows: “[t]he act, use, or employment by any person of any deception, deceptive act or practice, fraud, false pretense, false promise, misrepresentation, or concealment, suppression or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale or advertisement of any merchandise whether or not any person has in fact been misled, deceived, or damaged thereby . . .” § 44-1522(A).

544. The term “deceptive” has been interpreted to include representations that have a “tendency and capacity” to convey misleading impressions to consumers even though interpretations that would not be misleading also are possible.

545. Technical correctness of the representations is irrelevant if the capacity to mislead is found. Additionally, a deceptive representation or practice may be found where earlier misrepresentations are corrected before the consumer agrees to a contract.

546. The unconscionable, unfair and deceptive acts and practices described herein are declared unlawful under the Arizona CFA.

547. The CFA authorizes any person, including “a natural person, corporation, . . .” to seek an injunction, damages, costs, and reasonable attorneys’ fees to prevent and remedy the unfair and deceptive conduct described herein.

548. Mallinckrodt marketed and sold Acthar in Arizona pursuant to the marketing and sales scheme alleged, at the inflated prices set forth herein.

549. Members of Plaintiff Class who purchased and/or reimbursed the cost of Acthar at these inflated prices in Arizona are persons under the CFA. Each has been injured as a direct



and proximate result of Mallinckrodt's unconscionable, unfair, and deceptive conduct in violation of the CFA, and each hereby seeks damages, through their representative Local 420.

**Arkansas Deceptive Trade Practices Act ("ADTPA")**  
**Ark. Code § 4-88-101, *et seq.***

550. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of Ark. Code § 4-88-101, *et seq.*

551. Among other things, Ark. Code Ann. § 4-88-107 prohibits "[k]nowingly making a false representation as to the characteristics, ingredients, uses, benefits, alterations, source, sponsorship, approval, or certification of goods or services. . . ." and prohibits "[a]dvertising the goods or services with the intent not to sell them as advertised. . . ." Ark. Code Ann. § 4-88-107 (a)(1) & (3).

552. Under Ark. Code Ann. § 4-88-113 (f), a private cause of action is afforded to any person who suffers actual damage or injury.

553. The unconscionable, unfair and deceptive acts and practices described herein are declared unlawful under the ADTPA.

554. The ADTPA authorizes any person, including "a natural person, corporation, . . ." to seek an injunction, damages, costs, and reasonable attorneys' fees to prevent and remedy the unfair and deceptive conduct described herein.

555. Mallinckrodt marketed and sold Acthar in Arkansas pursuant to the marketing and sales scheme alleged, at the inflated prices set forth herein.

556. Members of Plaintiff Class who purchased and/or reimbursed the cost of Acthar at these inflated prices in Arkansas are persons under the ADTPA. Each has been injured as a direct and proximate result of Mallinckrodt's unconscionable, unfair, and deceptive conduct in violation of the ADTPA, and each hereby seeks damages, through their representative Local 420.

**California Business and Professions Code (“Section 17200”),  
Cal. Bus. & Prof. Code § 17200, et seq**

557. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of Cal. Bus. & Prof. Code § 17200, et seq.

558. Section 17200 is violated if a business practice is unlawful or unfair or deceptive. “[A] practice is prohibited as ‘unfair’ or ‘deceptive’ even if not ‘unlawful’ and vice versa.”

559. To show that a business practice is deceptive, the plaintiff must show that members of the public are likely to be deceived.

560. The deceptive business practices prong of Section 17200 does not require establishing that anyone was actually deceived, relied on the fraudulent practice or sustained any damage.

561. The unconscionable, unfair and deceptive acts and practices described herein are declared unlawful under Section 17200.

562. Section 17200 authorizes any person, including “a natural person, corporation, ...” to seek an injunction, damages, costs, and reasonable attorneys’ fees to prevent and remedy the unfair and deceptive conduct described herein.

563. Questcor was originally based in California and marketed and sold Acthar throughout California pursuant to the marketing and sales scheme alleged, at the inflated prices set forth herein. Mallinckrodt, now based in New Jersey, has continued such conduct.

564. Members of Plaintiff Class who purchased and/or reimbursed the cost of Acthar at these inflated prices in California are persons under Section 17200. Each has been injured as a direct and proximate result of Mallinckrodt’s unconscionable, unfair, and deceptive conduct in violation of Section 17200, and each hereby seeks damages, through their representative Local 420.

**Colorado Consumer Protection Act (CCPA),  
Colo. Rev. Stat. § 6-1-105, et seq.**

565. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices or has made false representations in violation of Colo. Rev. Stat. § 6-1-105, et seq.

566. To establish a claim under the Colorado Consumer Protection Act (CCPA), a private citizen must prove five elements: (1) the defendant engaged in an unfair or deceptive trade practice; (2) the deceptive trade practice occurred in the course of the defendant's business; (3) the deceptive trade practice significantly impacted the public as actual or potential customers of the defendant's business; (4) the plaintiff suffered an injury to a legally protected interest; and (5) the deceptive trade practice caused the plaintiff's injury.

567. The unconscionable, unfair and deceptive acts and practices described herein are thus unlawful under CCPA. Mallinckrodt engaged in the unfair and deceptive trade practices described herein, which deceptive trade practices occurred in the course of the defendant's business. The deceptive trade practice significantly impacted the public as actual or potential customers of the defendant's business. Members of the Class who purchased Acthar in Colorado suffered an injury to a legally protected interest by their payment of money for a drug that was unapproved, unsafe, ineffective and cost more than other equally or more effective medicines. The deceptive trade practice thus caused the plaintiff's injury.

568. Mallinckrodt marketed and sold Acthar in Colorado pursuant to the marketing and sales scheme alleged, at the inflated prices set forth herein.

569. Members of Plaintiff Class who purchased and/or reimbursed the cost of Acthar at these inflated prices in Colorado are persons under the CCPA. Each has been injured as a direct and proximate result of Mallinckrodt's unconscionable, unfair, and deceptive conduct in violation of the CCPA, and each hereby seeks damages, through their representative Local 420.

**Connecticut Unfair Trade Practices Act (“CUTPA”),  
Conn. Gen. Stat. § 42-110b, et seq.**

570. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of Conn. Gen. Stat. § 42-110b, et seq.

571. The CUTPA expressly admonishes that “[n]o person shall engage in unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce.” Conn. Gen. Stat. § 42-110b(a). The same section also provides that “[i]t is the intent of the legislature that in construing subsection (a) if this section [that] the courts of this state shall be guided by interpretations given by the [FTC] and the federal courts to Section 5(a)(1) of the Federal Trade Commission Act.

572. The unconscionable, unfair and deceptive acts and practices described herein are declared unlawful under the CUTPA.

573. The CUTPA authorizes any person, including “a natural person, corporation, limited liability company, trust, partnership, incorporated or unincorporated association, and any other legal entity” to seek an injunction, damages, costs, and reasonable attorneys’ fees to prevent and remedy the unfair and deceptive conduct described herein.

574. Members of the Class who purchased Acthar at inflated prices are persons pursuant to the CUTPA and each has been injured as a result of the Defendants’ unconscionable, unfair, and deceptive conduct in violation of the CUTPA, and hereby seeks damages. One such person is Sheet Metals Workers Local 40 of Hartford Connecticut (“SMW Local 40”), represented by the same undersigned Plaintiff counsel. SMW Local 40 has sued separately in Connecticut state court.

575. The facts and circumstances described herein demonstrate that Mallinckrodt acted unlawfully within the meaning of the CUTPA such that members of the Class may be awarded

actual damages sustained as well as punitive damages, and such additional, equitable relief as deemed necessary or proper.

576. Plaintiff and the Class seek relief against Mallinckrodt for its unconscionable, unfair, and deceptive commercial practices with regard to their scheme to sell Acthar to patients through KOLs at inflated prices by an unfair and deceptive scheme involving kickbacks and other inducements.

577. Mallinckrodt created restrictions on trade and commerce in Connecticut through the creation of the exclusive arrangement for the distribution and sale Acthar.

578. Mallinckrodt then agreed to raise the prices of Acthar to inflated levels, and charged such prices in Connecticut to TPPs like SMW Local 40. As described herein, Mallinckrodt charged the supracompetitive prices of Acthar through the ASAP Program.

579. This unconscionable, unfair, and deceptive conduct caused members of the Class in Connecticut, like SMW Local 40, to pay prices for Acthar significantly greater than in an otherwise competitive market. Therefore, SMW Local 40 and members of the Class in Connecticut are entitled to relief under the CUTPA.

580. Plaintiff and the Class were injured as a direct and proximate result of the Mallinckrodt's conduct in violation of Connecticut law and hereby seek declaratory and injunctive relief and damages.

**Consumer Fraud Act ("Delaware CFA"),  
Del. Code Ann. tit. 6, § 2513**

581. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of 6 Del. Code § 2511, et seq.

582. The unconscionable, unfair and deceptive acts and practices described herein are thus unlawful under Delaware CFA.

583. Mallinckrodt marketed and sold Acthar in Delaware pursuant to the marketing and sales scheme alleged, at the inflated prices set forth herein.

584. Specifically, the beneficiary of Local 420 resides in Delaware. Although she treated with a rheumatologist in Pennsylvania, she was obligated to pay a copay for Acthar.

585. Members of Plaintiff Class who purchased and/or reimbursed the cost of Acthar at these inflated prices in Delaware are persons under the CFA. Each has been injured as a direct and proximate result of Mallinckrodt's unconscionable, unfair, and deceptive conduct in violation of the CFA, and each hereby seeks damages, through their representative Local 420 and its Delaware-based beneficiary.

**District of Columbia Consumer Protection Procedures ("DCCPP")  
D.C. Code § 28-3904, *et seq.***

586. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices or made false representations in violation of D.C. Code § 28-3904, *et seq.*

587. D.C. Code § 28-3904 states "[i]t shall be a violation of this chapter for any person to engage in an unfair or deceptive trade practice, whether or not any consumer is in fact misled, deceived, or damaged thereby."

588. The unconscionable, unfair and deceptive acts and practices described herein are declared unlawful under the DCCPP.

589. The DCCPP authorizes any person, including "a natural person, corporation, ..." to seek an injunction, damages, costs, and reasonable attorneys' fees to prevent and remedy the unfair and deceptive conduct described herein.

590. Mallinckrodt marketed and sold Acthar in Arkansas pursuant to the marketing and sales scheme alleged, at the inflated prices set forth herein.

591. Members of Plaintiff Class who purchased and/or reimbursed the cost of Acthar at these inflated prices in the District of Columbia are persons under the DCCPP. Each has been injured as a direct and proximate result of Mallinckrodt's unconscionable, unfair, and deceptive conduct in violation of the DCCPP, and each hereby seeks damages, through their representative Local 420.

**Florida Deceptive & Unfair Trade Practices Act ("FDUTPA")**  
**Florida Stat. §§ 501.201, et seq.**

592. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of Fla. Stat. § 501.201, et seq.

593. The primary policy of the FDUTPA is "[t]o protect the consuming public and legitimate business enterprises from those who engage in unfair methods of competition, or unconscionable, deceptive, or unfair acts or practices in the conduct of any trade or commerce." Florida Stat. §§ 501.202(2).

594. A claim for damages under the FDUTPA has three elements: (1) a prohibited practice; (2) causation; and (3) actual damages.

595. Under Florida law, indirect purchasers of prescription drugs, like Plaintiff and the Class, have standing to maintain an action under the FDUTPA based on the facts alleged in this Complaint. Undersigned counsel for Plaintiff represents purchasers of Acthar located within Florida, who have decided to bring suit on their own behalf in Florida state court under FDUTPA.

596. Mallinckrodt's conduct constitutes an unfair method of competition and unfair and deceptive acts or practices because Mallinckrodt's conduct caused Florida-based members of the Class to pay artificially inflated prices for Acthar.

597. Mallinckrodt sold Acthar in Florida through the ASAP Program, based out of Orlando Florida, through Express Scripts subsidiary companies located in Florida, including United BioSource and Curascript. Such sales in Florida took place under the circumstances and conditions described in this Complaint, and Mallinckrodt's conduct had a direct and substantial impact on trade and commerce in Florida. Accordingly, such conduct falls within the prohibitions in Florida Stat. §§ 501.202(2).

598. The unconscionable, unfair and deceptive acts and practices described herein are declared unlawful under the FDUPA.

599. Members of Plaintiff Class who purchased and/or reimbursed the cost of Acthar at these inflated prices in Florida have standing to sue under the FDUPA. Each has been injured as a direct and proximate result of Mallinckrodt's unconscionable, unfair, and deceptive conduct in violation of the FDUPA, and each hereby seeks damages, through their representative Local 420.

**Georgia Fair Business Practices Act ("FBPA")**  
**Ga. Code Ann. §§ 10-1-390, et seq.**

600. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of Ga. Code § 10-1-393, et seq.

601. Ga. Code § 10-1-393(a) "[u]nfair or deceptive acts or practices in the conduct of consumer transactions and consumer acts or practices in trade or commerce are declared unlawful."

602. Mallinckrodt's conduct constitutes unfair or deceptive acts or practices in the trade or commerce of Georgia. Specifically, as described in part above, Tennessee-based Dr. Tumlin travelled to Georgia on multiple occasions as a Mallinckrodt paid KOL to promote



Mallinckrodt's misleading and deceptive message about Acthar's MOA and FDA approval, especially for NS. In fact, Dr. Tumlin travelled to suburban Atlanta for one such session.

603. As a result, doctors in Georgia became Mallinckrodt KOLs. One such doctor, Dr. Wilson, is described by former Mallinckrodt employee Barry Franks as having been part of the Mallinckrodt scheme to promote Acthar. Dr. Wilson treated a beneficiary of one of the Georgia-based clients of undersigned Plaintiff counsel. To date, such client has incurred over \$2 million in payments for Acthar, and continues to do so. The patient being treated with Acthar by Dr. Wilson is being treated for what is believed to be an off-label indication of NS. Specifically, the patient has been prescribed Acthar as a maintenance medication for the treatment of NS for multiple years. For his work on behalf of Mallinckrodt, Dr. Wilson has been paid thousands of dollars. Mallinckrodt has paid for Dr. Wilson to travel to multiple vacation locations as its "consultant" and has paid all the costs of such trips, as well as thousands of dollars of "consultant" fees and "honoraria".

604. Mallinckrodt's conduct caused Georgia-based members of the Class to pay artificially inflated prices for Acthar.

605. The unconscionable, unfair and deceptive acts and practices described herein are declared unlawful under the Georgia FBPA.

606. Members of Plaintiff Class who purchased and/or reimbursed the cost of Acthar at these inflated prices in Georgia have standing to sue under the FBPA. Each has been injured as a direct and proximate result of Mallinckrodt's unconscionable, unfair, and deceptive conduct in violation of the FBPA, and each hereby seeks damages, through their representative Local 420.

**Hawaii Unfair and Deceptive Trade Practice Act ("UDAP"),  
Haw. Rev. Stat. § 480, et seq.**

607. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of Haw. Rev. Stat. § 480, et seq.

608. Haw. Rev. Stat. § 480-2(a) states that “[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce are unlawful”.

609. The unconscionable, unfair and deceptive acts and practices described herein are declared unlawful under the Hawaii UDAP.

610. Mallinckrodt marketed and sold Acthar in Hawaii pursuant to the marketing and sales scheme alleged, at the inflated prices set forth herein

611. Only consumers, the attorney general, or the director of the office of consumer protection may bring a UDAP claim. HRS § 480-2(d). Consumers include those who “(1) purchased, attempted to purchase, or been solicited to purchase goods or services from the defendant, or (2) committed money, property, or services in a personal investment.”

612. Members of Plaintiff Class who purchased and/or reimbursed the cost of Acthar at the inflated prices set by Mallinckrodt and charged in Hawaii are persons under the Hawaii UDAP. Each has been injured as a direct and proximate result of Mallinckrodt’s unconscionable, unfair, and deceptive conduct in violation of the Hawaii UDAP, and each hereby seeks damages, through their representative Local 420.

613. The Hawaii UDAP also provides that “[a]ny consumer who is injured by any unfair or deceptive act or practice forbidden or declared unlawful by section 480-2: (1) May sue for damages sustained by the consumer, and, if the judgment is for the plaintiff, the plaintiff shall be awarded a sum not less than \$ 1,000 or threefold damages by the plaintiff sustained, whichever sum is the greater, and reasonable attorneys fees together with the costs of suit; and

(2) May bring proceedings to enjoin the unlawful practices, and if the decree is for the plaintiff, the plaintiff shall be awarded reasonable attorneys fees together with the cost of suit.”

614. Thus, it is not necessary that any Hawaii consumer suffered actual injury from their receipt and/or purchase of Acthar. As the Hawaii Supreme Court has held, “the plain language of the statute reflects that the legislature intended not only to protect persons who actually purchased goods or services as a result of unfair or deceptive acts and practices, but also those who attempted or were solicited to do so. ... The \$1,000.00 assured minimum recovery manifests a legislative intent to do more than simply prevent unjust enrichment at the expense of consumers who purchased relatively inexpensive goods.” *Zanakis-Pico v. Cutter Dodge, Inc.*, 98 Haw. 309, 316, 317 (2002).

**Idaho Consumer Protection Act (ICPA),  
Idaho Code § 48-601, *et seq***

615. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of Idaho Code § 48-601, *et seq*.

616. Idaho Code § 48-603 provides that “[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce are hereby declared to be unlawful...”

617. The ICPA was enacted to protect consumers from "deceptive acts and practices in the conduct of trade or commerce." I.C. § 48-601. "[T]he ICPA defines what constitutes an unfair method of competition." *State ex rel. Wasden v. Daicel Chem. Indus., Ltd.*, 141 Idaho 102, 107, 106 P.3d 428, 433 (2005).

618. Under I.C. §48-603, “deceptive acts or practices in the conduct of any trade or commerce are unlawful where a person knows, or in the exercise of due care should know, that he has in the past, or is:

- (2) Causing likelihood of confusion or of misunderstanding as to the source, sponsorship, approval, or certification of goods or services;
- (3) Causing likelihood of confusion or of misunderstanding as to affiliation, connection, or association with, or certification by, another;
- (5) Representing that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities that they do not have ...;
- (11) Making false or misleading statements of fact concerning the reasons for, existence of, or amounts of price reductions;
- (17) Engaging in any act or practice which is otherwise misleading, false, or deceptive to the consumer;
- (18) Engaging in any unconscionable method, act or practice in the conduct of trade or commerce, as provided in section 48-603C, Idaho Code ...

I.C. § 48-603 (2)-(3), (5), (11), (17)-(18)(statute excerpted for relevant portions only).

619. Section 48-603C defines “unconscionable methods, acts or practices” as follows:

- i. Any unconscionable method, act or practice in the conduct of any trade or commerce violates the provisions of this chapter whether it occurs before, during, or after the conduct of the trade or commerce.
- ii. In determining whether a method, act or practice is unconscionable, the following circumstances shall be taken into consideration by the court:
  - (a) Whether the alleged violator knowingly or with reason to know, took advantage of a consumer reasonably unable to protect his interest because of physical infirmity, ignorance, illiteracy, inability to understand the language of the agreement or similar factor;
  - (b) Whether, at the time the consumer transaction was entered into, the alleged violator knew or had reason to know that the price grossly exceeded the price at which similar goods or services were readily available in similar transactions by similar persons, although price alone is insufficient to prove an unconscionable method, act or practice;
  - (c) Whether the alleged violator knowingly or with reason to know, induced the consumer to enter into a transaction that was excessively one-sided in favor of the alleged violator;
  - (d) Whether the sales conduct or pattern of sales conduct would outrage or offend the public conscience, as determined by the court.

620. Beyond these legislative definitions of unfair competition, I.C. § 48-604 instructs that “[i]t is the intent of the legislature that in construing [the ICPA] due consideration and great weight shall be given to the interpretation of the federal trade commission and the federal courts

relating to section 5(a)(1) of the federal trade commission act (15 U.S.C. 45(a)(1)), as from time to time amended.”

621. Section 5(a)(1) of the FTCA provides that “[u]nfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce, are hereby declared unlawful.” 15 U.S.C. § 45(a)(1). “Federal case law as it has developed under this provision of the [FTCA], although not binding is persuasive in application of the [ICPA].” *State ex rel. Kidwell v. Master Distribs., Inc.*, 101 Idaho 447, 453, 615 P.2d 116, 122 (1980).

622. The acts and omissions of Mallinckrodt set forth herein violate the ICPA in multiple respects.

623. First, like the similar subsections of the Pennsylvania UTPCPL, Mallinckrodt’s actions violate the above-cited enumerated subsections of I.C. § 48-603 (2)-(3), (5), (11), (17)-(18).

624. Second, like the similar provisions of New Jersey law below, Mallinckrodt’s actions constitute unconscionable business practices because (1) Mallinckrodt “knowingly or with reason to know, took advantage of a consumer reasonably unable to protect his interest because of physical infirmity due to the diseases for which they were prescribed Acthar; (2) “at the time the consumer transaction was entered into, [Mallinckrodt] knew or had reason to know that the price [for Acthar] grossly exceeded the price at which similar goods or services were readily available in similar transactions by similar persons,” given the substantially cheaper costs of prednisone and other steroids; (3) Mallinckrodt “knowingly or with reason to know, induced the consumer to enter into a transaction that was excessively one-sided in favor of the alleged violator”, in light of the role of the Mallinckrodt HUB, the MSLs, the KOLs, the PAPs and other aspects of Mallinckrodt’s scheme to ensure sales of Acthar at high prices; and (4) the fact that

“the sales conduct or pattern of sales conduct would outrage or offend the public conscience”, as determined by the court based on, among other things, the Acthar price change from \$40.00 to over \$40,000 for a drug with limited uses and benefits.

625. Members of Plaintiff Class who purchased and/or reimbursed the cost of Acthar at these inflated prices in Idaho are consumers under the ICPA. Each has been injured as a direct and proximate result of Mallinckrodt’s unconscionable, unfair, and deceptive conduct in violation of the ICPA, and each hereby seeks damages, through their representative Local 420.

**Illinois Consumer Fraud and Deceptive Business Practices Act,  
815 ILCS § 505/1, *et seq***

626. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of 815 ILCS § 505/1, *et seq*.

627. 815 ILCS § 505/2 states that “[u]nfair methods of competition and unfair or deceptive acts or practices, including but not limited to the use or employment of any deception fraud, false pretense, false promise, misrepresentation or the concealment, suppression or omission of any material fact, with intent that others rely upon the concealment, suppression or omission of such material fact, or the use or employment of any practice described in Section 2 of the "Uniform Deceptive Trade Practices Act", approved August 5, 1965, in the conduct of any trade or commerce are hereby declared unlawful whether any person has in fact been misled, deceived or damaged thereby. In construing this section consideration shall be given to the interpretations of the Federal Trade Commission and the federal courts relating to Section 5 (a) of the Federal Trade Commission Act.”

628. The unconscionable, unfair and deceptive acts and practices described herein are declared unlawful under the Illinois Act.

629. The Illinois Act authorizes any person, including “a natural person, corporation, ...” to seek an injunction, damages, costs, and reasonable attorneys’ fees to prevent and remedy the unfair and deceptive conduct described herein.

630. Mallinckrodt marketed and sold Illinois in Alabama pursuant to the marketing and sales scheme alleged, at the inflated prices set forth herein.

631. Members of Plaintiff Class who purchased and/or reimbursed the cost of Acthar at these inflated prices in Illinois are persons under the Illinois Act. Each has been injured as a direct and proximate result of Mallinckrodt’s unconscionable, unfair, and deceptive conduct in violation of the Illinois Act, and each hereby seeks damages, through their representative Local 420.

**Kansas Unfair Trade and Consumer Protection,  
Kan. Stat. § 50-623**

632. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of Kan. Stat. § 50-623, et seq.

633. Kan. Stat. § 50-626(a) states that [n]o supplier shall engage in any deceptive act or practice in connection with a consumer transaction; Kan. Stat. § 50-626(b): “[d]eceptive acts and practices include, but are not limited to, the following, each of which is hereby declared to be a violation of this act, whether or not any consumer has in fact been misled”: (3) “the will failure to state a material fact, or the willful concealment, suppression or omission of a material fact”; (7) “making false or misleading representations, knowingly or with reason to know, of fact concerning the reason for, existence of or amounts of price reductions, or the price in comparison to prices of competitors or one’s own price at a past or future time”; (8) “falsely stating, knowingly or with reason to know, that a consumer transaction involves consumer rights, remedies or obligations”.



634. Under Kan. Stat. § 50-627(a), “[u]nconscionable acts and practices, [n]o supplier shall engage in any unconscionable act or practice in connection with a consumer transaction. An unconscionable act or practice violates this act whether it occurs before, during or after the transaction.”

635. Kan. Stat. § 50-627(b)(1) states that “[t]he supplier took advantage of the inability of the consumer reasonably to protect the consumer's interests because of the consumer's physical infirmity, ignorance, illiteracy, inability to understand the language of an agreement or similar factor”.

636. Kan. Stat. § 50-627(b)(2) states that “when the consumer transaction was entered into, the price grossly exceeded the price at which similar property or services were readily obtainable in similar transactions by similar consumers.”

637. Kan. Stat. § 50-627(b)(5) “the transaction the supplier induced the consumer to enter into was excessively one sided in favor of the supplier”.

638. Kan. Stat. § 50-627(b)(6) “the supplier made a misleading statement of opinion on which the consumer was likely to rely to the consumer’s detriment.”

639. The unconscionable, unfair and deceptive acts and practices described herein are declared unlawful under the Kansas law.

640. Kansas authorizes any person, including “a natural person, corporation, ... ” to seek an injunction, damages, costs, and reasonable attorneys’ fees to prevent and remedy the unfair and deceptive conduct described herein.

641. Mallinckrodt marketed and sold Acthar in Kansas pursuant to the marketing and sales scheme alleged, at the inflated prices set forth herein.



642. Members of Plaintiff Class who purchased and/or reimbursed the cost of Acthar at these inflated prices in Kansas are persons under the Kansas Act. Each has been injured as a direct and proximate result of Mallinckrodt's unconscionable, unfair, and deceptive conduct in violation of the Kansas Act, and each hereby seeks damages, through their representative Local 420.

**Kentucky Revised Statutes,  
Consumer Protection - Ky. Rev. Stat. § 367.110, *et seq.***

643. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of Ky. Rev. Stat. § 367.110, *et seq.*

644. Under Ky. Rev. Stat. § 367.170(1) “[u]nfair, false, misleading, or deceptive acts or practices in the conduct of any trade or commerce are hereby declared unlawful; (2) [f]or the purposes of this section, unfair shall be construed to mean unconscionable.”

645. Ky. Rev. Stat. § 367.175(2) “[i]t shall be unlawful for any person or person to monopolize, or attempt to monopolize or combine or conspire with any other person or persons to monopolize any part of the trade or commerce in this Commonwealth.”

**Louisiana Revised Statutes – Unfair Trade Practices and Consumer Protection Law  
La. Rev. Stat. § 51:1401, *et seq***

646. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of La. Rev. Stat. § 51:1401, *et seq.*

647. Under La. Rev. Stat. § 51:1405(A) “[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce are hereby declared unlawful.”

**Maine Unfair Trade Practices Act,  
5 Me. Rev. Stat. § 207, *et seq***

648. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of 5 Me. Rev. Stat. § 207, *et seq*.

649. 5 Me. Rev. Stat. § 207 “Unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce are declared unlawful.” 5 Me. Rev. Stat. § 207(1) “[T]he courts will be guided by the interpretations given by the Federal Trade Commission and the Federal Courts to Section 45(a)(1) of the Federal Trade Commission Act (15 United States Code 45(a)(1))...”.

**Maryland Consumer Protection Act,  
Md. Com. Law Code § 13-101, *et seq***

650. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of Md. Com. Law Code § 13-101, *et seq*.

651. Maryland Unfair or deceptive trade practices include “[f]alse, falsely disparaging, or misleading oral or written statement, visual description, or other representation of any kind which has the capacity, tendency, or effect of deceiving or misleading consumers”. Md. Com. Law Code § 13-301(1). Any representation “fail[ing] to state a material fact if the failure deceives or tends to deceive” is unlawful. Md. Com. Law Code § 13-301(3).

652. “A price in comparison to price of a competitor or to one’s own price at a past or future time”. Md. Com. Law Code § 13-301(6)(ii).

653. Md. Com. Law Code § 13-301(9) “Deception, fraud, false pretense, false premise, misrepresentation, or knowing concealment, suppression, or omission of any material fact with the intent that consumer rely on the same in connection with (i) [t]he promotion or sale of any consumer goods, consumer realty or consumer service”.

**Massachusetts Consumer Protection Act (“MCPA”)  
Mass. Gen. L. Ch. 93A, et seq.**

654. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of Mass. Gen. L. Ch. 93A, et. seq. (“MCPA”).

655. The MCPA regulates trade and commerce “directly or indirectly affecting the people of this commonwealth.” Mass. Gen. L. Ch. 93A § 9(1).

656. Under the MCPA, “[a]ny person, who has been injured by another person’s use or employment of any method, act or practice” that constitutes “[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce.” Mass. Gen. L. Ch. 93A §§ 2, 9(1). MCPA § 2(b) provides that these terms are interpreted consistent with Section 5 of the FTC Act (15 U.S.C. § 45(a)), which also prohibits “[u]nfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce.” Mass. Gen. L. Ch. 93A § 2(b); 15 U.S. § 45(a)(1).

657. Defendants’ conduct constitutes an unfair method of competition and unfair and deceptive acts or practices because Defendants’ conduct cause Plaintiff and the Class to pay artificially inflated prices for Acthar.

658. Mallinckrodt sold Acthar in Massachusetts under the circumstances and conditions described in this Complaint, and its conduct had a direct and substantial impact on trade and commerce in Massachusetts. Accordingly, such conduct falls within the prohibitions in Ch. 93A § 2.

659. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of Mass. Gen. L. Ch. 93A, et seq.

**Michigan,  
Mich. Stat. § 445.901, et seq.**

660. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of Mich. Stat. § 445.901, et seq.

661. Mich. Stat. § 445.901, et seq.

**Minnesota**  
**Minn. Stat. § 8.31, et seq.**

662. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of Minn. Stat. § 8.31, et seq.

**Missouri Merchandising Practices Act (“MMPA”),**  
**Mo. Rev. Stat. 407.020**

663. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of the Missouri Merchandising Practices Act (“MMPA”), Mo. Rev. Stat. 407.020.

664. Under Section 407.020, the MMPA prohibits “[t]he act, use or employment by any person of any deception, fraud, false pretense, false promise, misrepresentation, unfair practice or the concealment, suppression, or omission of any material fact in connection with the sale or advertisement of any merchandise in trade or commerce.” Mo. Rev. Stat. 407.020.

665. The Missouri Attorney General has defined an “unfair practice” as:

any practice which . . . [o]ffends any public policy as it has been established by the Constitution, statutes or common law of this state, or by the Federal Trade Commission, or its interpretive decisions; or . . . [i]s unethical, oppressive, or unscrupulous; and . . . [p]resents a risk of, or causes, substantial injury to consumers.

Mo. Att’y Gen. Reg., 15 CSR 60-8.02.

666. Mallinckrodt’s conduct constitutes an unfair method of competition and unfair and deceptive acts or practices because Mallinckrodt’s conduct caused Plaintiff and the Class to pay artificially inflated prices for Acthar.

**Montana,  
Mont. Code § 30, 14-101, *et seq.***

667. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of Mont. Code § 30, 14-101, *et seq.*

**Nebraska,  
Rev. Stat. § 59-1601, *et seq.***

668. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of Neb. Rev. Stat. § 59-1601, *et seq.*

**Nevada,  
Nev. Rev. Stat. § 598.0903, *et seq.***

669. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of Nev. Rev. Stat. § 598.0903, *et seq.*

**New Hampshire,  
N.H. Rev. Stat. § 358-A:1, *et seq.***

670. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of N.H. Rev. Stat. § 358-A:1, *et seq.*

**New Mexico,  
N.M. Stat. § 57-12-1, *et seq.***

671. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of N.M. Stat. § 57-12-1, *et seq.*

**New York (“Donnelly Act”),  
N.Y. Gen. Bus. Law § 349 *et seq.***

672. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of N.Y. Gen. Bus. Law § 349 *et seq.*

**North Carolina (“Chapter 75”),  
N.C. Gen. Stat. § 75-1.1, *et seq.***

673. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of N.C. Gen. Stat. § 75-1.1, et seq.

**North Dakota,**  
N.D. Cent. Code § 51-15-01, *et seq.*

674. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of N.D. Cent. Code § 51-15-01, et seq.

**Ohio,**  
**Ohio Rev. Stat. § 1345.01, *et seq.***

675. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of Ohio Rev. Stat. § 1345.01, et seq.

676. Dr. Mandel lives and works in Ohio, along with Mallinckrodt's Chris Sender. The acts and omissions of Dr. Mandel and Mallinckrodt described herein, in addition to those described in the Franks Complaint, demonstrate multiple violations of Ohio law.

**Oklahoma**  
**Okla. Stat. 15 § 751, *et seq.***

677. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices or made false representations in violation of Okla. Stat. 15 § 751, et seq.

**Oregon**  
**Or. Rev. Stat. § 646.605, *et seq.***

678. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of Or. Rev. Stat. § 646.605, et seq.

**Rhode Island**  
**R.I. Gen. Laws § 6-13.1-1, *et seq.***

679. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of R.I. Gen. Laws § 6-13.1-1, et seq.

**South Carolina**

**S.C. Code Laws § 39-5-10, *et seq.***

680. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of S.C. Code Laws § 39-5-10, *et seq.*

**South Dakota  
S.D. Code Laws § 37-24- 1, *et seq.***

681. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of S.D. Code Laws § 37-24- 1, *et seq.*

**Tennessee  
Tenn. Code § 47-18-101, *et seq.***

682. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of Tenn. Code § 47-18-101, *et seq.*

**Texas  
Tex. Bus. & Com. Code § 17.41, *et seq.***

683. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of Tex. Bus. & Com. Code § 17.41, *et seq.*

**Utah  
Utah Code § 13-11-1, *et seq.***

684. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of Utah Code § 13-11-1, *et seq.*

**Vermont's Consumer Fraud Act ("Vermont CFA"), Vt. Stat. Ann. tit. 9, § 2451**

685. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of 9 Vt. § 2451, *et seq.*

686. The express statutory purpose of the Vermont CFA is to "protect the public" against "unfair or deceptive acts or practices." Vt. Stat. Ann. tit. 9, § 2451. Its purpose is remedial, and as such the court applies the Act liberally to accomplish its purposes.

687. To establish a “deceptive act or practice” under the Vermont CFA requires three elements: (1) there must be a representation, omission, or practice likely to mislead consumers; (2) the consumer must be interpreting the message reasonably under the circumstances; and (3) the misleading effects must be material, that is, likely to affect the consumer's conduct or decision regarding the product. Vt. Stat. Ann. tit. 9, § 2453(a).

688. Deception is measured by an objective standard, looking to whether the representation or omission had the “capacity or tendency to deceive” a reasonable consumer; actual injury need not be shown. To be reasonable, moreover, the consumer’s understanding need not be the only one possible; “if an ad conveys more than one meaning to reasonable consumers and one of those meanings is false, that ad may be condemned.” Furthermore, the Act “does not require a showing of intent to mislead, but only an intent to publish the statement challenged.”

689. Materiality is also generally measured by an objective standard, premised on what a reasonable person would regard as important in making a decision; it may include a subjective test, however, where the seller knows that the consumer, because of some peculiarity, is particularly susceptible to an omission or misrepresentation.

690. Where the seller knew, or should have known, that an ordinary consumer would need omitted information to evaluate the product or service, or that the claim was false, materiality will be presumed because the manufacturer intended the information or omission to have an effect.

**Virginia**  
**Va. Code § 59.1-196, et seq.**

691. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of Va. Code § 59.1-196, et seq.



**Washington**  
**Wash. Rev. Code § 19.86.010, et seq**

692. Mallinckrodt has engaged in unfair competition or unfair, deceptive or fraudulent acts or practices in violation of Wash. Rev. Code § 19.86.010, et seq.

**West Virginia**  
**West Virginia Code § 46A-6-101, et seq.**

693. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of West Virginia Code § 46A-6-101, et seq.

**WHEREFORE**, Steamfitters Local Union No. 420 demands that judgment be entered in its favor and against Mallinckrodt in an amount to be determined at trial, under the consumer fraud laws of these states, including but not limited to costs, attorneys' fees, and such other relief deemed just and appropriate by this Court.

**COUNT V**  
**NEGLIGENT MISREPRESENTATION**

694. Plaintiff hereby incorporates by reference the preceding and following averments as if fully set forth herein and further alleges as follows.

695. Defendants' acts violate Pennsylvania common law against negligent misrepresentation, as well as the common law of negligence of other states where members of the Class reside.

696. Negligent misrepresentation requires proof of (1) a misrepresentation of a material fact; (2) made under circumstances in which the misrepresenter ought to have known of its falsity; (3) with an intent to induce another to act on it; and (4) which results in injury to a party acting in justifiable reliance on the misrepresentation.

697. Defendants made misrepresentations of material fact, as detailed herein. For instance, in setting and communicating the AWP-based prices for Acthar, which prices Local

420 paid, the Defendants made material misrepresentations that those prices represented a calculation of real and fact-based prices for their drugs, and that they represented the actual value of the product in the marketplace. Defendants called these prices “average wholesale prices” and when they knew they were not. They did so intending to induce Plaintiff and members of the Class to pay such “average wholesale prices” for Acthar, and Local 420 and the Class in fact, justifiably relied upon such prices in paying them.

698. As set forth herein, Mallinckrodt made multiple misrepresentations about the value of Acthar, in relation to the high prices it set for Acthar. Mallinckrodt knew that these representations were false, yet they made them intending to induce payors like Plaintiff and the Class to pay for Acthar. Plaintiff and the Class, in fact, justifiably relied on such statements of value, as Acthar was placed on lists of “specialty” drugs, by pharmacy benefits managers, like Future Scripts, for which deep discounts on brands and generics were unavailable.

699. These representations were material to the transactions at hand in that Local 420 used and relied upon the inflated prices for Acthar as the basis for the amount to pay and/or reimburse for Acthar under the specialty drug provisions of its agreements with IBC and Future Scripts.

700. Defendants knew or should have known of the falsity of their misrepresentations, especially as to the purported value of Acthar. Mallinckrodt bought Acthar for \$100,000 when it was selling for only \$40. Having spoken about the purported value of Acthar in relation to its high pricing Mallinckrodt and its KOLs had a duty to speak the truth about the lack of value for new indications.

701. As set forth more fully above, the prices communicated by Defendants to payors like Plaintiff through the ASAP and UBC HUB were artificial prices, unrelated to any actual,

reasonable price in the marketplace, or actual value of Acthar. Instead, they were intentionally created and manipulated by the Defendants for the purpose of generating exorbitant revenue, thus constituting false representations which the Defendants knew or, in the absence of recklessness, should have known to be false.

702. The Defendants made these misrepresentations about the actual prices for and value of Acthar with the intent of misleading Local 420 and the Class into relying on the prices as real and fact-based prices, rather than artificially inflated prices.

703. Local 420 and the Class justifiably relied upon these false misrepresentations in purchasing and/or reimbursing Acthar at the amount charged by Mallinckrodt through its ASAP and HUB based on the prices it set in 2007 and beyond. As a result, Plaintiff was injured by paying more for Acthar than it should have.

704. The Pennsylvania Supreme Court has expressly adopted several aspects of the Restatement (Second) of Torts relevant to the claims of Plaintiff and the Class. For instance, Section 552, which is titled “Information Negligently Supplied for the Guidance of Others”, provides, in pertinent part: (1) one who, in the course of his business, profession, or employment, or in any other transaction in which he has a pecuniary interest, supplies false information for the guidance of others in their business transactions, is subject to liability for pecuniary loss caused to them by their justifiable reliance upon the information, if he fails to exercise reasonable care or competence in obtaining or communicating the information. (2) ...[T]he liability stated in (1) is limited to loss suffered (a) by the person or one of a limited group of persons for whose benefit and guidance he intends to supply the information or knows that the recipient intends to supply it; and (b) through reliance upon it in a transaction that he intends the information to influence or

knows that the recipient so intends or in a substantially similar transaction.” *Bitt-Rite Contrs, Inc., v. Architectural Studio*, 581 Pa. 454, 459 n.1, 866 A.2d. 270 (2005).

705. Here, Mallinckrodt and UBC are “expert suppliers of information” about Acthar which information is widely disseminated to the public in general, and the medical community in particular, in order to induce justifiable reliance on the information being supplied. They hold themselves out to the public as such experts. Mallinckrodt is the manufacturer of Acthar, and an expert to whom patients (like the Plaintiff’s-beneficiary who took Acthar), payers (like Plaintiff and the Class), doctors (like the prescribers of the Acthar here), PBMs (like Express Scripts) and others look for information about value, pricing and safety of its drugs.

706. UBC is a self-described “HUB” of information about Acthar, its uses, benefits and prices. It is the Mallinckrodt’s designated interface between the providers, patients, and third party payors, as well as the manufacturer. Mallinckrodt trains UBC RSs about Acthar, which information UBC then shares with patients, payors and providers.

707. Mallinckrodt and UBC supplied information described herein “in the course of [their] business, profession, or employment”. They supplied misleading and deceptive information for the guidance of the Local 420 patients and the Plaintiff itself, as well as the Class, in course of business transactions involving the distribution, sales and payment for Acthar. Plaintiff and the Class justifiably relied on such information in paying the high prices for Acthar being charged in 2018.

708. Mallinckrodt and UBC failed to exercise reasonable care or competence in the promulgation of misleading and deceptive information about the value of Acthar, as evidenced by Express Scripts’ 2017 revelations that Acthar was not worth what was being charged for it. Plaintiff and the Class are entitled to recover for their losses suffered, since Local 420 and its

beneficiary, as well as the Class of third party payors, are persons for whose benefit and guidance Defendants intended to supply the information of Acthar value and the Defendants knew or should have known Local 420 and its beneficiary, as well as the Class, would receive such information and rely upon it.

709. As a direct and proximate result of the misrepresentations of Mallinckrodt, as set forth above, Local 420 and the Class were harmed in that they justifiably relied on the negligent misrepresentations about the value of Acthar in relation to its high prices.

710. Plaintiff and the Class were unaware of the artificial, inflated prices of Acthar, and would not have paid and/or reimbursed the artificially inflated prices for Acthar had they known of the misrepresentations of material fact made by Defendants. Plaintiff and the Class overpaid for the Acthar because of such misrepresentations.

**WHEREFORE**, Steamfitters Local Union No. 420 demands that judgment be entered in its favor, and in favor of the Class, and against Defendants, in an amount to be determined at trial, including but not limited to costs, attorneys' fees, and such other relief deemed just and appropriate by this Court.

**COUNT VI**  
**AIDING AND ABETTING/CONSPIRACY**

711. Plaintiff hereby incorporates by reference the preceding and following averments as if fully set forth herein and further alleges as follows.

712. As set forth more fully above, beginning at least as early as 2007, the exact date being unknown to the Plaintiff and the Class, and continuing thereafter until the present, Defendants and other unnamed co-conspirators (including providers who acted as KOLs for Defendants), between and among themselves and others, entered into an agreement and/or otherwise engaged in a continuing conspiracy to defraud and deceive the Plaintiff and the Class

by causing it to pay more for Acthar than it otherwise would have paid in the absence of the Defendants' conspiracy and concerted action.

713. Pursuant to the unfair and deceptive schemes to distribute, price and market Acthar at high prices, which bore no reasonable relation to the value of the drug as ascribed to it in 2017 by Express Scripts, and the conspiracy alleged herein, and in furtherance thereof, Defendants and their co-conspirators engaged in a wide range of activities, the purpose and effect of which was to defraud, deceive and misinform Local 420 and the Class as to the truth about Acthar pricing and value, and acted or took substantial steps in furtherance of the conspiracy. Those acts include the following:

- a. discussing and agreeing among themselves and with their co-conspirators that they would control and communicate the price at which Local 420 and the Class paid for Acthar far above the reasonable value of the drug;
- b. discussing and agreeing among themselves and with their co-conspirators that they would increase the price at which Local 420 and the Class paid for Acthar;
- c. discussing and agreeing among themselves and with their co-conspirators that they would jointly implement and directly control the ASAP program, and associated materials and website, which enrolled patients into an exclusive distribution network for the administration of Acthar, allowing Defendants to raise the prices unchecked and to conduct their unfair pricing scheme for Acthar;
- d. discussing and agreeing among themselves and with their co-conspirators that they would directly control the exclusive distribution network for Acthar through the ASAP Program and the UBC "HUB",
- e. discussing and agreeing among themselves and with their co-conspirators that they would rely on employees to promote the ASAP Program through the marketing alleged herein;
- f. discussing and agreeing among themselves and with their co-conspirators that they would conceal and suppress the truth about the Acthar inflated prices, the Acthar true value, and the monies

earned from payors like Local 420 and the Class.

714. In addition to the specific facts set forth above, it is alleged the Defendants and their co-conspirators engaged in conspiratorial meetings, among the purposes of which meetings were to discuss the importance of controlling the direct distribution, marketing, sale and administration of Acthar to payors like Local 420 and the Class, and deriving substantial profits from these activities. These meetings took place in the summer of 2007, when Defendants were negotiating the contracts that form their exclusive agreement. The meetings and communications continued thereafter when Mallinckrodt and UBC agreed to raise the prices for Acthar to its current exorbitant levels, and communicate those inflated prices to patients and TPPs. They have also taken place after Relators sued.

715. There was a common design pursuant to which Defendants carried out their tortious acts of negligently misrepresenting the truth about Acthar, and the acts or practices in violation of the consumer fraud laws. The common designed involved, among other things, misleading patients and payors, like Plaintiff and the Class, about the value of Acthar in relation to its high prices, and concealing the truth about Acthar and their exclusive arrangements.

716. There was a common design pursuant to which Defendants carried out their tortious acts of negligently misrepresenting the truth about Acthar and their exclusive arrangements, and the acts or practices in violation of the consumer fraud laws. The common design involved, among other things, misleading patients and payors, like Plaintiff and the Class, about the value of Acthar in relation to its high prices, and concealing the truth about Acthar and their exclusive arrangements.

717. Here, Mallinckrodt aided and abetted its sales representatives, including MSLs, and multiple doctors engaged as KOLs in unlawful acts, practices, misrepresentations, omissions



and deception, knowing that they were breaching their duty to tell the truth, having spoken publicly about Acthar, its uses and benefits, and its price. Mallinckrodt aided and abetted providers in breaching their obligations to patients covered by Plaintiff and the Class by continuing to conceal and suppress the truth about Acthar's lack of value. Mallinckrodt gave substantial assistance to sales representatives and KOLs in accomplishing their tortious conduct, and their conduct in so assisting, breached a separate duty owed to the Plaintiff and the Class.

718. UBC aided and abetted Mallinckrodt in their schemes by serving as the HUB and direct interface with patients and payors to ensure that Acthar prescriptions were filled and paid for at inflated AWP as set by Mallinckrodt.

719. The Defendants performed the conspiratorial acts set forth herein intending to injure payors of Acthar, like Local 420 and the Class, by causing them to pay inflated prices so that the Defendants could derive substantial profits.

720. The Defendants performed the acts alleged herein in furtherance of the common plan or design for the conspiracy with intent and/or with knowledge of the injury and damage it would cause to Local 420 and the Class, and with knowledge and intent to cause such injuries and/or with reckless disregard for the consequences. These acts were either unlawful (as in the case of the acts described in Counts I, II and III) or lawful by an unlawful means as for an unlawful purpose (as in the case of Defendants' willful silence in the face of its co-conspirators' misinformation and misrepresentations).

721. As a direct and proximate result of the Defendants' conspiracy and aiding and abetting as alleged herein, Local 420 and the Class have been injured and damaged, and the Defendants are jointly and severally liable for such injuries and damages.

**WHEREFORE**, Steamfitters Local Union No. 420 demands that judgment be entered in



its favor, and in favor of the Class and against Defendants, in an amount to be determined at trial, including but not limited to costs, attorneys' fees, and such other relief deemed just and appropriate by this Court.

## **COUNT VII**

### **UNJUST ENRICHMENT**

722. Plaintiff hereby incorporates by reference the preceding and following averments as if fully set forth herein and further alleges as follows.

723. This Count alleges unjust enrichment against Mallinckrodt.

724. Like the beneficiaries in the Class, Local 420's covered beneficiary received direct shipments of Acthar from Mallinckrodt via its exclusive distribution mechanism established with CuraScript and UBC. In exchange for such Acthar, Local 420 and the Class made payments to Mallinckrodt, through UBC. The amount charged by Mallinckrodt for Acthar was the amount paid by Local 420 and the Class pursuant to their agreements with their healthcare plans.

725. The amounts paid by Local 420 and the Class were valuable to Mallinckrodt and UBC, and both Mallinckrodt and UBC were unjustly enriched by such payments, in that, the reimbursement rates charged by Mallinckrodt were valuable and beneficial to Mallinckrodt, and Mallinckrodt compensated UBC out of such funds.

726. By engaging in the conduct described herein, Mallinckrodt and UBC have knowingly obtained benefits from Local 420 and the Class, namely, grossly inflated revenue from their direct involvement in coordinating all aspects of the receipt of and payments for Acthar, under circumstances such that it would be inequitable and unjust for Mallinckrodt and UBC to retain such benefits.

727. Mallinckrodt and UBC were able to extract exorbitant revenue from Local 420 and the Class beyond what either could have received in the absence of their unlawful conduct. This conduct violated the consumer protection laws of Pennsylvania and other states, as well as the common laws of Pennsylvania and other states, and, as such, interfered with the legally protected interests of Local 420 and the Class.

728. Local 420 and each member of the Class are therefore entitled to an award of compensatory damages in an amount to be determined at trial, or the imposition of a constructive trust upon the monies derived by the Defendants by means of the above-described actions.

729. By engaging in the unlawful conduct described herein, Mallinckrodt and UBC have been knowingly enriched by the amount charged for Acthar over and above what they could have charged in a competitive market.

**WHEREFORE**, Steamfitters Local Union No. 420 demands that judgment be entered in its favor, and in favor of the Class, and against Mallinckrodt, in an amount to be determined at trial, including but not limited to costs, attorneys' fees, and such other relief deemed just and appropriate by this Court.

**COUNT VIII**  
**DECLARATORY AND INJUNCTIVE RELIEF**

730. Plaintiff hereby incorporates by reference the preceding and following averments as if fully set forth herein and further alleges as follows.

731. Plaintiff has alleged an interest which, insofar as it paid inflated prices for Acthar, is substantial and immediate insofar as it has had to pay exorbitant prices for Acthar in 2018. There is a reasonable likelihood that Plaintiff will have to pay for Acthar in the future, especially given Mallinckrodt's and UBC's marketing efforts to expand Acthar prescriptions into new indications, like the rheumatic disorder suffered by its beneficiary.

732. Thus, Plaintiff has alleged a real, actual controversy with Defendants that requires immediate attention. The public has already shown an interest in the Acthar lawsuit being litigated in Rockford, Illinois. Thus, Plaintiff's request for declaratory and injunctive relief does not seek merely an abstract or advisory opinion.

733. Plaintiff and the Class hereby request that the acts and practices set forth herein be declared unlawful under the consumer fraud laws and/or the common law of negligent misrepresentation, regardless of the quantum of damages suffered individually by Plaintiff and the Class, the precise calculation of which will have to await discovery. This will inure to the benefit of Plaintiff, its beneficiaries, the members of the coalition of which Plaintiff is a part, and self-funded payors, everywhere in the Class who have paid, are paying, or will pay in the future for Acthar.

734. Plaintiff and the Class also request the issuance of an injunction to enjoin Mallinckrodt and UBC from conspiring and agreeing to raise the prices of Acthar above competitive levels, and from charging such inflated prices. The injunction should also prohibit Mallinckrodt and UBC from engaging in the unlawful practices alleged herein.

735. An injunction is needed to prevent immediate and irreparable harm that cannot be compensated adequately by damages. Plaintiff and the Class will be irreparably harmed if an injunction does not timely issue because patients are put at risk as payors like Plaintiff and the Class are forced to decide about whether to cover all the new indications for which Mallinckrodt and UBC are marketing Acthar. Further, because multiple, individual actions would be required to bring about what one injunction in this action could accomplish, there is an inadequate legal remedy. Plaintiff has no adequate remedy at law to prevent Defendants from furthering acting to

harm itself and its patient-beneficiaries due to the unchecked nature of their pricing decisions, which have been demonstrated to be far above any reasonable “value” assessment.

736. Greater injury would result from refusing the injunction than from granting it, as patients and payors like Plaintiff will continue to be threatened by new prescriptions of Acthar at exorbitant price levels, threatening patient care. The issuance of an injunction will not substantially harm Mallinckrodt or UBC, because Mallinckrodt and UBC will continue to sell Acthar for all the approved indications, albeit at lower prices.

737. The injunction will properly restore the parties to where they were before the unlawful conduct was begun by Defendants.

738. Plaintiff has a clear right to relief and is likely to prevail on the merits, which this case is related to and which at least Mallinckrodt has indicated a willingness to settle rather than fight.

739. The injunction, as will be framed in an appropriate motion to the court, will be reasonably suited to abate the offending activity only.

740. The public interest will not be adversely affected by the injunction. To the contrary, the public interest will be served by stopping the unlawful practices by Mallinckrodt.

741. All the requisite elements for issuance of an injunction have been, and will be, met.

### **PRAYER FOR RELIEF**

WHEREFORE, Steamfitters Local Union No. 420 and the Class request the Court to enter the following relief:

- a. Declare unlawful the acts and practices alleged herein, enjoin Mallinckrodt from committing the acts alleged herein, and restore the status quo before the unlawful conduct took place;

- b. Enter judgment Mallinckrodt and UBC for the violations alleged herein;
- c. Certify a Class of all third party payors and their beneficiaries;
- d. Award the actual damages incurred by Plaintiff and the Class as a result of the wrongful acts complained of, along with pre-judgment and post-judgment interest at the maximum rate allowed by law;
- e. Award statutory damages set forth herein under the statutory claims alleged;
- f. Award treble damages or multiple damages by operation of law;
- g. Award punitive damages;
- h. Award Plaintiff and the Class the costs of this action, including reasonable attorney's fees, and, where applicable, expert fees; and
- i. Award such other and further relief as the Court may deem just and appropriate.

### **JURY DEMAND**

Steamfitters Local Union No. 420 and the Class hereby demand a trial by jury of all issues so triable in this cause.

Respectfully submitted,

Date: July 12, 2019

By: /s/ Donald E. Haviland, Jr  
Donald E. Haviland, Jr., Esquire  
(PA ID No. 66616)  
William H. Platt II, Esquire  
(PA ID No. 83585)  
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Phone: (215) 609-4661

*Counsel for Plaintiff,  
Steamfitters Local Union No. 420  
and the Class*

# EXHIBIT 3

INTERNATIONAL UNION OF OPERATING : IN THE MONTGOMERY COUNTY  
ENGINEERS LOCAL 542 : COURT OF COMMON PLEAS

v.

MALLINCKRODT ARD, INC., formerly :  
known as QUESTCOR : No. 2018-14059  
PHARMACEUTICALS, INC.

MALLINCKRODT PLC

EXPRESS SCRIPTS HOLDING COMPANY

EXPRESS SCRIPTS, INC.  
CURASCRIPT, INC.

CURASCRIPT SD

ACCREDITO HEALTH GROUP, INC.

and

UNITED BIOSOURCE CORPORATION, now :  
known as UNITED BIOSOURCE LLC., a :  
wholly owned subsidiary of UNITED :  
BIOSOURCE HOLDINGS, INC.

### **OBJECTIONS TO SUBPOENAS PURSUANT TO RULE 4009.21**

Defendants Mallinckrodt ARD Inc. and Mallinckrodt plc (collectively, "Mallinckrodt") object to the proposed subpoenas directed to (1) Dr. Irene Greenhouse, M.D.; (2) Dr. Gary W. Clauser, M.D.; and (3) Dr. Steven Urbaniak, D.O. (collectively, the "Physician Subpoenas") that are attached collectively as Exhibit "A" to these objections for the following reasons:

1. The three identical Physician Subpoenas – which seek documents far outside the permissible bounds of discovery, as detailed further herein – are designed to cause, and would cause, unreasonable annoyance, embarrassment, and burden as they improperly seek the personal health information for an unknown number of individuals who are entirely unrelated to Plaintiff and its claims against Defendants.

2. The Physician Subpoenas also will improperly harass and annoy these non-party physicians and cause them cause unreasonable burden and harm Mallinckrodt's relationship with the prescribing physicians, thus potentially impacting Mallinckrodt's business.

3. The Physician Subpoenas also will improperly cause embarrassment to these non-party physicians and interfere with the patient-physician relationship by insinuating that an unapproved or off-label use of Acthar would be inappropriate when, to the contrary, a physician is well within his or her right to prescribe Acthar based on his or her expert knowledge, treatment experience, and patient response.

4. The Physician Subpoenas further cause unreasonable annoyance and burden as they are not appropriately limited in time or scope, amounting to an untargeted fishing expedition in the files of these non-parties.

5. The Physician Subpoenas further improperly seek information that is in the possession of Mallinckrodt or other Defendants and is thus readily available to Plaintiff through regular discovery requests without needlessly harassing and burdening the uninvolved non-parties.

6. The Physician Subpoenas are beyond the scope of permissible discovery set forth in Rule 4003.1 in that they are not reasonably calculated to lead to the discovery of admissible evidence and improperly seek production of documents not remotely relevant to this lawsuit. For example, and without limitation, the Physician Subpoenas seek information relating to:

- Acthar prescriptions for multiple sclerosis, despite multiple sclerosis being mentioned only once in the Amended Complaint (¶ 154) and not remotely connected to the four patients that Plaintiff International Union of Operating Engineers Local 542 ("Plaintiff") insures;

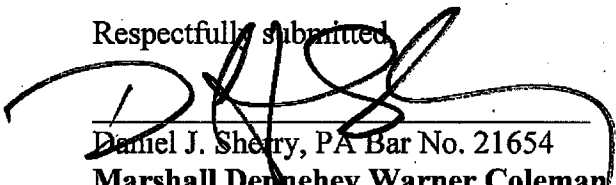


- Off-label treatments and unapproved uses and doses, despite no mention of unapproved dosing and a single allegation (§ 45) relating to off-label treatment for infantile spasms, which clearly does not relate to Plaintiff's adult patients;
- Physician-attended meetings and educational seminars, despite no alleged conduct relating to such meetings;
- Mallinckrodt's relationship with the three physicians, despite the Amended Complaint naming none of these physicians nor alleging that these physicians treated the patients at issue in the suit or that Mallinckrodt (or any other Defendant for that matter) had an improper relationship with the physicians;
- The three physicians' relationship and dealing with Acthar and *any* patients, despite only four patients being associated with Plaintiff and mentioned in the Amended Complaint none of which are alleged to have been treated by these physicians; and
- Mallinckrodt sales representatives, despite allegations in the Amended Complaint stating that "all aspects of Acthar distribution and sales were handled by Express Scripts" (§§ 50, 169).

WHEREFORE, Defendants Mallinckrodt ARD Inc. and Mallinckrodt plc object to Plaintiff's proposed subpoenas directed to (1) Irene Greenhouse, M.D.; (2) Gary W. Clauser, M.D.; and (3) Steven Urbaniak, D.O. and respectfully request that the Court sustain their objections, preclude Plaintiff International Union of Operating Engineers Local 542 from issuing the proposed subpoenas, and grant such other and further relief as the Court deems appropriate.

Date: July 25, 2019

Respectfully submitted,



Daniel J. Sherry, PA Bar No. 21654

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*Counsel for Mallinckrodt ARD Inc. and  
Mallinckrodt plc*

**CERTIFICATE OF SERVICE**

Daniel J. Sherry, Esquire hereby certifies that a true and correct copy of the foregoing Objections To Subpoenas Pursuant To Rule 4009.21 was electronically filed and forwarded to the following via email and/or United States First Class Mail, postage prepaid, on July 25, 2019:

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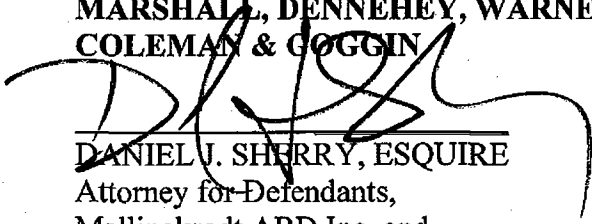
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**MARSHALL, DENNEHEY, WARNER,  
COLEMAN & GOGGIN**

  
DANIEL J. SHERRY, ESQUIRE  
Attorney for Defendants,  
Mallinckrodt ARD Inc. and  
Mallinckrodt plc

# EXHIBIT “A”

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*Counsel for Plaintiff,*

*International Union of Operating Engineers*

*Local 542*

**IN THE COURT OF COMMON PLEAS  
FOR MONTGOMERY COUNTY, PENNSYLVANIA**

**INTERNATIONAL UNION OF  
OPERATING ENGINEERS LOCAL 542**

**Plaintiff,**

**v.**

**MALLINCKRODT ARD, INC., *et al.***

**Defendants.**

Civil Action No. 2018-14059

**NOTICE OF INTENT TO SERVE A SUBPOENA TO PRODUCE  
DOCUMENTS AND THINGS FOR DISCOVERY  
PURSUANT TO RULE 4009.21**

Plaintiff intends to serve a subpoena identical to the one that is attached to this notice.

You have twenty (20) days from the date listed below in which to file of record and serve upon the undersigned an objection to the subpoena. If no objection is made, the subpoena may be served.

Respectfully submitted,

Dated: July 11, 2019

By: *s/ Donald E. Haviland, Jr.*

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*International Union of Operating Engineers*

*Local 542*

**INTERNATIONAL UNION OF  
OPERATING ENGINEERS LOCAL 542**

Plaintiff,

v.

**MALLINCKRODT ARD, INC., et al.**

Defendants.

Civil Action No. 2018-14059

**CERTIFICATE OF SERVICE**

I, Donald E. Haviland, Jr. hereby certify that on this 11th day of July, 2019, a true and correct copy of the attached Notice of Intent to Serve Subpoena was served upon the following parties via electronic mail and first-class mail as follows:

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s/ Donald E. Haviland, Jr.  
Donald E. Haviland, Jr., Esq.

## IN THE COURT OF COMMON PLEAS OF MONTGOMERY COUNTY

International Union of Operating :  
 Enginners Local 542, :  
 Plaintiff :

v.

: File No. 2018-14059

Mallinckrodt ARD, INC., et al, :  
 Defendants. :

**SUBPOENA TO PRODUCE DOCUMENTS OR THINGS  
 FOR DISCOVERY PURSUANT TO RULE 4009.21**

TO: Steven Urbaniak, D.O. 940 Town Center Dr., Suite F50,  
 (Name of Person or Entity) Langhorne, PA 19047

Within twenty (20) days after service of this subpoena, you are ordered by the court to produce the following documents or things:

See Attachment "A".

at Haviland Hughes, 201 S. Maple Way, Suite 100, Ambler PA 19002  
 (address)

You may deliver or mail legible copies of the documents or produce things requested by the subpoena, together with the certificate of compliance, to the party making this request at the address listed above. You have the right to seek in advance the reasonable cost of preparing the copies or producing the things sought.

If you fail to produce the documents or things required by this subpoena within (20) days after its service, the party serving this subpoena may seek a court order compelling you to comply with it.

**THIS SUBPOENA WAS ISSUED AT THE REQUEST OF THE FOLLOWING PERSON:**

NAME: Donald E. Haviland, Jr., Esq.

ADDRESS: 201 S. Maple Way, Suite 100

Ambler, PA 19002

TELEPHONE: 215-609-4661

SUPREME COURT ID#: 66615

ATTORNEY FOR: Plaintiff, IUOE Local 542

BY THE COURT:

Mark Levy, Prothonotary

DATE: \_\_\_\_\_

Seal of the Court

BY: 

Agent/Deputy

**RETURN OF SERVICE:**

On the \_\_\_\_\_ day of \_\_\_\_\_, 20\_\_\_\_

I, \_\_\_\_\_

served \_\_\_\_\_

(NAME OF PLACE SERVED)

with the foregoing subpoena by:

(Describe method of service)

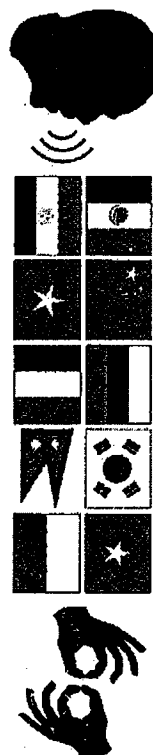
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

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DATE: \_\_\_\_\_

(SIGNATURE)

**Notice of Language Rights**



**FREE INTERPRETER**

PO Box 311 Northtown, PA 19404  
languageaccesscoordinator@montcopa.org  
610-278-3231

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**HAVILAND HUGHES**

BY: s/Donald E. Haviland, Jr.  
Donald E. Haviland, Jr.

Donald E. Haviland, Jr., Esquire (PA I.D. #66615)

*haviland@havilandhughes.com*

William H. Platt II, Esquire (PA I.D. #83585)

*platt@havilandhughes.com*

**HAVILAND HUGHES**

201 South Maple Way, Suite 110

Ambler, PA 19002

(215) 609-4661 Telephone

(215) 392-4400 Facsimile

*Counsel for Plaintiff,*

*International Union of Operating Engineers*

*Local 542*

**IN THE COURT OF COMMON PLEAS  
FOR MONTGOMERY COUNTY, PENNSYLVANIA**

**INTERNATIONAL UNION OF  
OPERATING ENGINEERS LOCAL 542**

Plaintiff,

v.

**MALLINCKRODT ARD, INC., *et al.***

Defendants.

Civil Action No. 2018-14059

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PURSUANT TO RULE 4009.21**

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Respectfully submitted,

Dated: July 11, 2019

By: *s/ Donald E. Haviland, Jr.*

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*haviland@havilandhughes.com*

William H. Platt II

*platt@havilandhughes.com*

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**INTERNATIONAL UNION OF  
OPERATING ENGINEERS LOCAL 542**

Plaintiff,

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Defendants.

Civil Action No. 2018-14059

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Bryan Cave Leighton Paisner, LLP  
One Atlantic Center, 14<sup>th</sup> Floor  
1201 W. Peachtree Street, NW  
Atlanta, GA 30309  
*Patrick.watson@bcplaw.com*  
*Lindsayjohnson@bcplaw.com*

Herbert R. Giorgio, Jr., Esquire  
Bryan Cave Leighton Paisner, LLP  
One Metropolitan Square  
211 North Broadway, Suite 3600  
St. Louis, MO 63102  
*herb.giorgio@bcplaw.com*



Philip D. Bartz, Esquire  
Bryan Cave Leighton Paisner, LLP  
1155 F. Street, N.W.  
Washington, D.C. 20004  
Philip.bartz@bclplaw.com

Joseph P. Walsh, Esquire  
Walsh Pancio  
2028 North Broad Street  
Lansdale, PA 19446  
joe@walshpancio.com

Daniel J. Sherry, Esquire  
Wendy J. Bracaglia, Esquire  
Marshall, Dennehey, Warner, Coleman & Goggin  
620 Freedom Business Center, Suite 300  
King of Prussia, PA 19406  
djsherry@mdwgc.com  
wjbracaglia@mdwgc.com

Matthew M. Martino, Esquire  
Evan Kreiner, Esquire  
Michael Menitove, Esquire  
Skadden, Arps, Slate, Meagher & Flom, LLP  
Four Times Square  
New York, NY 10036-6522  
Matthew.Martino@skadden.com  
Evan.Kreiner@skadden.com  
Michael.Menitove@skadden.com

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Donald E. Haviland, Jr., Esq.

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TO: Gary W. Clauser, M.D. 1250 S. Cedar Crest Blvd., Suite 405  
(Name of Person or Entity) Allentown, PA 18103

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TELEPHONE: 215-609-4661SUPREME COURT ID#: 66615ATTORNEY FOR: Plaintiff, IUOE Local 542

BY THE COURT:

Mark Levy, Prothonotary

DATE: \_\_\_\_\_

Seal of the Court

BY: 

Agent/Deputy

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served \_\_\_\_\_  
(NAME OF PLACE SERVED)

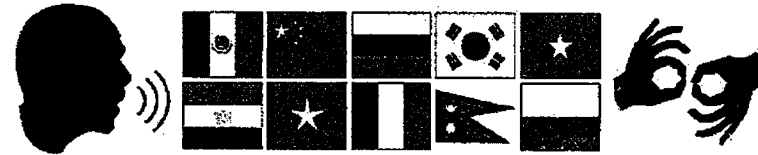
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(Describe method of service)

\_\_\_\_\_  
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*Counsel for Plaintiff,*

*International Union of Operating Engineers*

*Local 542*

**IN THE COURT OF COMMON PLEAS  
FOR MONTGOMERY COUNTY, PENNSYLVANIA**

**INTERNATIONAL UNION OF  
OPERATING ENGINEERS LOCAL 542**

Plaintiff,

v.

**MALLINCKRODT ARD, INC., et al.**

Defendants.

Civil Action No. 2018-14059

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Michael.Menitove@skadden.com

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Donald E. Haviland, Jr., Esq.

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International Union of  
Operating Engineers Local 542

v.

: File No. 2018-14059

Mallinckrodt ARD, Inc. et al.

SUBPOENA TO PRODUCE DOCUMENTS OR THINGS  
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(Name of Person or Entity) Jamison, PA 18929

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BY THE COURT:

Mark Levy, Prothonotary

DATE: \_\_\_\_\_

Seal of the Court

BY: 

Agent/Deputy

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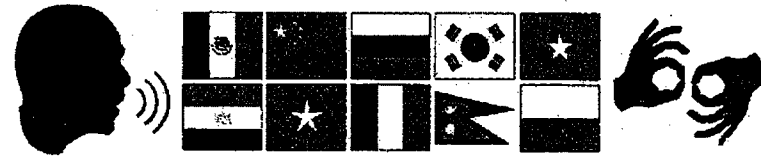
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Donald E. Haviland, Jr.

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INTERNATIONAL UNION OF OPERATING  
ENGINEERS LOCAL 542

Plaintiff,

v.

Civil Action No. 2018-14059

MALLINCKRODT ARD, INC., *et al.*

Defendants.

**DEFENDANTS MALLINCKRODT ARD, INC.'S AND MALLINCKRODT PLC'S  
MEMORANDUM IN SUPPORT OF THEIR OPPOSITION TO PLAINTIFF'S MOTION  
TO STRIKE MALLINCKRODT'S OBJECTIONS TO SUBPOENAS**

**I. MATTER BEFORE THE COURT**

Plaintiff International Union of Operating Engineers Local 542's ("Plaintiff") Motion to Strike Defendants Mallinckrodt ARD, Inc.'s and Mallinckrodt plc's (collectively, "Mallinckrodt") objections to Plaintiff's subpoenas for production of documents ("Subpoenas") on three physicians: Dr. Irene Greenhouse, M.D., Dr. Gary W. Clauser, M.D., and Dr. Steven Urbaniak, D.O. ("the Physicians").

**II. QUESTION PRESENTED**

Do Plaintiff's Subpoenas seek information that is irrelevant, not reasonably calculated to lead to the discovery of admissible evidence, and are the requests overly broad and unduly burdensome?

**Suggested Answer: Yes.**

### III. BACKGROUND

This case is about Mallinckrodt's and co-defendant Express Scripts Inc.'s distribution and sale of Acthar, a product used to treat many serious medical conditions. Plaintiff is a "union fund providing health and welfare benefits to its members and their families." Ex. 1, Am. Compl. ¶ 19. Plaintiff claims that "[t]his case . . . seeks to challenge the lawfulness of Mallinckrodt's exercise of its monopoly power . . . ." Ex. 1, Am. Compl. ¶ 4. Plaintiff alleges that Mallinckrodt's unlawful acts were: (i) "inflating the costs of Mallinckrodt's Acthar, which Plaintiff paid for under a contract with Express Scripts, and by concealing from IUOE Local 542 the true costs for Acthar through undisclosed, direct contractual arrangements between Mallinckrodt and Express Scripts;" and (ii) "acquiring the only competitive product in the marketplace, Synacthen . . . ." Ex. 1, Am. Compl. ¶¶ 4-5. Plaintiff does not challenge in this lawsuit the activity of physicians who have prescribed Acthar, any agreements between Mallinckrodt and physicians, or Mallinckrodt's marketing of Acthar.

Relevant to the instant Motion, Plaintiff's counsel has filed a separate lawsuit in the United States District Court for the Eastern District of Pennsylvania challenging, among other things, an alleged "scheme and RICO enterprise to bribe doctors in order to induce them to prescribe Acthar over other available treatments." Ex. 2, Complaint ¶ 12, *Steamfitters Local Union No. 420 v. Mallinckrodt ARD, LLC*, No. 2:19-cv-03047-BMS, ECF No. 1 (E.D. Pa. July 12, 2019). Defendants' motions to dismiss are pending in that lawsuit, and discovery has not commenced.

On July 11, 2019, Plaintiff served on Mallinckrodt notices of its intention to serve the Subpoenas on three physicians: Dr. Irene Greenhouse, M.D., Dr. Gary W. Clauser, M.D., and Dr. Steven Urbaniak, D.O. Each Subpoena contains 17 requests for the production of documents that

are unbound by any date restriction, and 13 of which are “all document” requests. Examples of specific requests include:

Request 1: All documents referring or relating to any meetings between [the physicians] and Mallinckrodt.

Request 4: All documents referring, relating to or reflecting Acthar treatment for unapproved uses or doses, such as 5-day dosing for multiple sclerosis.

Request 5: All documents referring, relating to or reflecting Acthar off label treatments.

Request 8: All documents related to meetings and communications between [the physicians] and any other doctor(s) regarding Acthar.

Request 9: All documents referring, relating to or received during continuing medical education (CME) seminars or meetings during which Acthar treatment was discussed.

On July 25, 2019, Mallinckrodt timely served objections to the Subpoenas. In summary, Mallinckrodt objected on the grounds that the requests in the Subpoenas are not reasonably calculated to lead to the discovery of admissible evidence, that service of the Subpoenas would cause unreasonable annoyance, embarrassment, and burden to the physicians, and that service of the Subpoenas would prejudice Mallinckrodt. Ex. 3, Mallinckrodt’s Objections to Subpoenas Pursuant to Rule 4009.21 ¶¶ 1, 6. Counsel for the parties conferred on September 24, 2019 and Mallinckrodt’s counsel sent Plaintiff’s counsel a letter on October 2, 2019 explaining that Mallinckrodt maintains its objections to the Subpoenas. Mot. Ex. B.

#### **IV. LEGAL ARGUMENT**

##### **A. Legal Standard**

A party may only take discovery “regarding any matter, not privileged, which is relevant to the subject matter involved in the pending action.” Pa. R. Civ. P. 4003.1(a). Discovery shall not be permitted which “would cause unreasonable annoyance, embarrassment, oppression, may



not be used to search for information which is not reasonably calculated to lead to the discovery of admissible evidence or which has no bearing on the subject matter involved in the underlying action.” *Office of the Dist. Attorney of Phila. v. Bagwell*, 155 A.3d 1119, 1138 (Pa. Commw. Ct. 2017). The Court must ensure discovery requests are “tailored to [the Plaintiff’s] specific [ ] cause of action” and do not constitute a “fishing expedition.” *Berkeyheiser v. A-Plus Investigations, Inc.*, 936 A.2d 1117, 1127 (Pa. Super. Ct. 2007); *see also Hoffman v. Knight*, 823 A.2d 202, 208 n.3 (“Courts liberally allow discovery, but ‘fishing expeditions’ under the guise of discovery are not tolerated.”). “Whether a subpoena shall be enforced rests in the judicial discretion of the court.” *In re Semeraro*, 515 A.2d 880, 882 (Pa. 1986) (citation omitted).

#### **B. The Subpoenas Seek Irrelevant Information**

Plaintiff contends that the information sought by the Subpoenas is relevant, but a cursory review of Plaintiff’s Amended Complaint (“Complaint”) and the allegations cited in the Motion reveal that that none of the information Plaintiff is seeking is relevant or could possibly lead to the production of admissible evidence. Plaintiff alleges: (i) Mallinckrodt engaged in unlawful activity related to its distribution of Acthar through Express Scripts and Express Scripts’ former pharmaceutical support services unit, UBC, and (ii) Mallinckrodt’s acquisition of Synacthen allegedly resulted in unlawfully higher prices for Acthar. Ex. 1, Am. Compl. ¶¶ 5, 6, 112. None of these issues involve physicians generally or the three targets of the proposed Subpoenas specifically. There are no allegations in the Complaint that any physician is involved in the contractual relationship between Mallinckrodt and its distributor of Acthar. Similarly, there are no allegations that physicians are involved in the pricing of Acthar. Likewise, there are no allegations that physicians were involved in Mallinckrodt’s acquisition of Synacthen. And, the

three Physicians who Plaintiff proposes to subpoena are not referenced in the Complaint. None of the documents requested by the Subpoenas could possibly shed light on any of the facts of this case.

Plaintiff cites six Complaint paragraphs in support of its argument that the broad requests in the Subpoenas seek relevant information. Mot. ¶ 10. The Motion fails to explain, however, why any of the Subpoena requests would lead to the discovery of admissible evidence concerning the allegations in the paragraphs cited or Plaintiff's claims as a whole. Not one of the paragraphs Plaintiff cites supports the discovery it seeks to impose on these non-parties. Just a cursory review of the cited allegations in the Complaint demonstrates why the Subpoenas are seeking irrelevant information.

- Paragraphs 6 and 11 describe Plaintiff's allegations that Plaintiff paid inflated prices for Acthar, and the amounts Plaintiff allegedly paid for Acthar. There is no mention of any physician involvement with the allegedly unlawful conduct, or any suggestion that any physician would have information relevant to the asserted claims. Nothing in these paragraphs suggests that the Physicians possess any information concerning the allegations or that the information sought in the Subpoenas could lead to the discovery of admissible information.
- The allegations in Paragraphs 53, 54 and 70 purport to describe the procedures that are required for the shipment of an Acthar prescription and the reimbursement for the cost of an Acthar prescription. While these paragraphs allege that physicians must submit prescriptions through the Acthar Support & Access Program ("ASAP") or use the "Acthar Start Form," Plaintiff offers no explanation for why discovery from non-parties is necessary to prove these allegations, which relate

entirely to processes allegedly set by the Defendants. Nothing in these paragraphs suggest the information requested in Plaintiff's wide-ranging Subpoenas will lead to the discovery of admissible evidence.

- Similarly, Paragraph 77 purports to quote a newspaper article that includes an alleged statement by Mallinckrodt's Executive Vice President describing Acthar market research. Plaintiff's Motion fails to explain how the Subpoena topics would yield potentially admissible evidence concerning Mallinckrodt's market research and how such evidence relates to Plaintiff's allegations that the pricing of Acthar was unlawful.

The Motion fails to show why, for example, these allegations warrant Plaintiff's wide-ranging requests to these non-party Physicians to produce, "[a]ll documents referring, relating to or reflecting Acthar treatment of unapproved uses and doses, such as 5-day dosing for multiple sclerosis" (Request 4), or "[a]ll documents referring, relating to or reflecting Acthar off label treatments" (Request 5). These are only two of many examples of requests that are far afield from the allegations Plaintiff cites in the instant motion.

Finally, Plaintiff's counsel appears to be seeking information from the Physicians through these Subpoenas to use in a *different case* alleging certain claims that are not asserted in this lawsuit. Plaintiff served its notice of intent to issue these Subpoenas on July 11, 2019. One day later, Plaintiff's counsel filed a class action complaint on behalf of Steamfitters Local Union No. 420 in the United States District Court for the Eastern District of Pennsylvania, which contains allegations concerning the three Physicians who are the potential recipients of the Subpoenas. Ex. 2, *Steamfitters* Compl. ¶¶ 312–385; 418–420.

The lack of relevance of the information requested in the Subpoenas, in combination with the timing of the Subpoenas and the allegations in the *Steamfitters* complaint, demonstrate that Plaintiff's counsel is attempting to use the discovery process in this case to try to support the claims of a different plaintiff in a separate federal action where discovery has not yet begun and where motions to dismiss are pending. The Court should not condone this "end run" around the procedures in federal court and the unnecessary burden on non-parties through this abuse of the discovery process in this case. The Subpoena topics are not seeking information that is reasonably calculated to lead to the discovery of admissible evidence *in this case*. Accordingly, the motion should be denied.

**C. The Subpoenas Are Overly Broad and Unduly Burdensome**

Even if the requests in the Subpoenas sought information relevant to this case (and they do not), the requests are overly broad and unduly burdensome. For example, many requests are not limited to Acthar or competing products. Three such requests include: "[a]ll documents referring or relating to any meetings and communications between You and Mallinckrodt" (Request 1), "[a]ll Your tax returns reflecting on money paid by Mallinckrodt to You" (Request 14), and "[a]ll documents relating to meetings and communications with Mallinckrodt sales representatives, including Stacyann Clancy and Art Veno" (Request 15), among others.

Even those requests that are limited to actions or communications related to Acthar are extremely broad. For example, Plaintiff requests "[a]ll documents referring, relating to or reflecting Your prescriptions of Acthar to patients with MS," (Request 3), "[a]ll documents related to meetings and communications between You and any other doctor(s) regarding Acthar" (Request 8), and "[a]ll documents referring, relating to or received during continuing medical education

(CME) seminars or meetings during which Acthar treatment was discussed” (Request 9), among others.

Furthermore, the Subpoenas place no limit on the time period for which they seek documents. If served, this would require the Physicians to search their records going back over their entire careers, well beyond the time period relevant to this case or reasonable to any document request.

The Motion fails to demonstrate that the Subpoena topics are narrowly tailored so as not to unreasonably burden these non-parties. Although “a limited degree of ‘fishing’ is to be expected with certain discovery requests, parties are not permitted ‘to fish with a net rather than with a hook or a harpoon.’” *Brogan v. Rosenn, Jenkins & Greenwald, LLP*, No. 08 CV 6048, 2013 WL 1742689, \*8 (Pa. Com. Pl. Apr. 22, 2013) (quoting *Brownstein v. Phila. Transp. Co.*, 46 Pa. D. & C.2d 463, 464 (Pa. Com. Pl. 1969)). Accordingly, Mallinckrodt’s objections should stand and the Motion should be denied.

#### **D. Mallinckrodt has Standing to Object to the Subpoenas**

Plaintiff argues that Mallinckrodt does not have standing to assert its objections. But, the Pennsylvania Rules of Civil Procedure provide Mallinckrodt with the ability and right to object to the Subpoenas. Pa. R. Civ. P. 4009.21(c). There is no dispute that Mallinckrodt followed the procedure afforded to it under the Rules when it asserted its objections.

Furthermore, Mallinckrodt will be harmed if these overbroad and unduly burdensome Subpoenas are served. Mallinckrodt desires that these three Physicians and other healthcare providers continue to prescribe Acthar and Mallinckrodt’s other medications. Burdening physicians with responding to overly broad Subpoenas that require significant effort, time, and expense will dissuade physicians from exercising their professional judgement to prescribe Acthar.

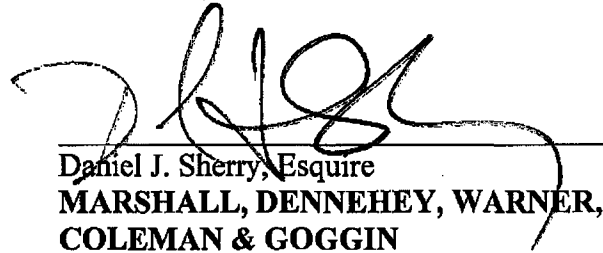
Therefore, allowing Plaintiff to proceed with these overbroad Subpoenas could lead to fewer prescriptions of Acthar, resulting in harm to Mallinckrodt's business.

**V. RELIEF REQUESTED**

Based on Mallinckrodt's response to the Motion and the arguments presented above, Mallinckrodt respectfully requests that the Court deny Plaintiff's Motion.

Dated: October 18, 2019

Respectfully submitted,



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